FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-90292 | Department: CFSAN | RCT No.: RCT-1186179 | CTU Triage Date: 11-Dec-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Dec-2023	CTU Received Date	08-Dec-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	
Section A	- About the Problem				
	nd of problem was it? all that apply)	Used a product incorrectly	e effect (including new or worsening symptor which could have or led to a problem quality of the product ng from one product maker to another maker		
Date the	e problem occurred	25-Jun-2023			
Serious	ki (j	Yes			
	of the following happen? all that apply)	Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important me	ermanent harm		
2 T 2 T 2 T 2 T 2 T 2 T 2	erious/important medical t(Please Describe Below)				
	vhat happened and hov onal documents if nece		as many details as possible Fi	DA may reach out to you for	
and the second se	Not subject to the local bid of the second	Contraction of the second s	lead levels result during her annual	physical test with her doctor.	

CFSAN CAERS PHONE REPORT 12/8/2023: We got high lead levels result during her annual physical test with her doctor. Second test July 11, 2023 Result through IV: 4.9; 9/27/2023 Result: 6.5; 10/31/2023: 4.9. We changed her food around 14 months, she has stop consuming pouches 3 months ago.

R	Relevant Test/Laboratory Data 1 of 1			
	Test Name	LEAD TEST FINGER POK E	Test Date	27-Jun-2023
	Test Result	8.6	Test Unit	MICROGRAMS PER DEC

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Low Test Range		High Test Range	
More Information Available?			
ditional Comments			
ction B - Product Availability	citate.		
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		and a contract
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WANABANA APPLE	CINNAMON	
Name of the company that makes (or compounds) the product	WANABANA		
Product Type(check all that apply)	Compounded by a Pha	rmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
ig Therapy			1 of 1
Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started	01-Dec-2022		

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Date the person stopped taking	30-Sep-2023
or using the product	
Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Why was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
Section D - About the Medical De	evice
Name of medical device	
Name of the company that	
makes the medical device Other identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ocate them)	interest, soundy, for, sonal, or oprintmoor, and the expiration date, in you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If
1	relevant)
Section E - About the Person Wh	on Had the Problem
Person's Initials	(b)(6)
Sex	Female
Gender	Not selected
Please Specify Other Gender	
Age (specify unit of time for age)	
Age (specify unit of time for age) Date of Birth	(b)(6)
and the second se	(b)(6) 8.55 kg
Date of Birth	

CTU No.: FDA-CDER-CTU-2023-90292 | Department: CFSAN | RCT No.: RCT-1186179 | CTU Triage Date: 11-Dec-2023 | Total Pag es: 5

22	Asian
	White
	Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

[List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Antibiotic; Medicated ear drops

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Tylenol, Ibiprophen

Section F - About the Perse	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code		
Telephone number	(b)(6)	
Email address		

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Fax		
Reporter Organization		t
Department		T
Reporter Speciality		Г
Today's date	08-Dec-2023	Г
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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CTU No.: FDA-CDER-CTU-2023-90845 | Department: CFSAN | RCT No.: RCT-1186821 | CTU Triage Date: 12-Dec-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	11-Dec-2023	CTU Received Date	12-Dec-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact			
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Sec	tion A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem occurred	27-Jul-2023	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My infant son (at the time of testing had just turned 1) had a high blood lead level. On 7/27/23 he had a finger prick lead test which came back at 8.5mcg/dl. he was retested with a venous draw on 7/31/23 and his levels came back at 6.8mcg/dl. prior to this, his grandmother had provided many pouches of the wana bana apple cinnamon puree. He has since not had any. At the time we assumed the lead poisoning was coming from our newly purchased home we are renovating. Our county did not come do any testing to find out even though it was requested by myself and two doctors. My son was removed from our new home while I worked on renovations and has been living with my mother and his father in my mothers home in a nearby town. On 11/10/23 I was tested for lead and it was found that I had none in my system. I have been living and working in the new house non stop, which leads me to believe that my son was poisoned by the cinnamon in the wana bana pouches. He had another finger prick lead test done on 10/25/23 and the value came back at <3.3mcg/dl. He has not experienced any noticable side effects as of yet.

Relevant Test/Laboratory (Data	19	1 of	4
Test Name	LEAD SCREEN (SON)	Test Date	27-Jul-2023	

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Test Result	8.5mcg/dl	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.0	High Test Range	4.9
More Information Available?		20	ation (
elevant Test/Laboratory D	ata	<i>\$</i>);	2 of 4
Test Name	LEAD, VENOUS (SON)	Test Date	31-Jul-2023
Test Result	6.8mcg/dl	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.0	High Test Range	4.9
More Information Available?		•	
elevant Test/Laboratory D	ata		3 of 4
Test Name	LEAD SCREEN (SON)	Test Date	25-Oct-2023
Test Result	<3.3mcg/dl	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.0	High Test Range	4.9
More Information Available?			
elevant Test/Laboratory D	ata	20	4 of 4
Test Name	LEAD, VENOUS (MOTHE R)	Test Date	10-Nov-2023
Test Result	0.0mcg/dl	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.0	High Test Range	4.9
More Information Available?			

Additional Comments

I have added which tests belonged to my son and the one that belonged to me, his mother.

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No	
Do you have a picture of the product? (check yes if you are including a picture)	No	

action C - About the Products		1 of 1
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report is about	Food/Medical food	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Apple Cinnamon Fruit Puree	

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CTU No.: FDA-CDER-CTU-2023-90845 | Department: CFSAN | RCT No.: RCT-1186821 | CTU Triage Date: 12-Dec-2023 | Total Pag es: 5

Name of the company that makes (or compounds) the product	Wana Bana			
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar			
Strength		If Other		
NDC number		Aus		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Jun-2023	12.		
Date the person stopped taking or using the product	31-Jul-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?				
Why was the person using the pr It is baby food.	oduct r (such as wha	at condition was it sup	posed to treat)	1 of 1
Returned to Manufacturer On				
Section D - About the Medical De	avice			1
Name of medical device				
Name of the company that				
makes the medical device				
Other identifying information (The locate them)	e model, catalog, lot,	serial, or UDI number	r, and the expiration d	ate, if you can
Model Number				

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Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

n or implanted medical devices of the righter as pacentakers, dreast implants, etc./				
Date the implant was put in	Date the implant was taken out (If relevant)			

Section E - About the Person Wh	to Had the Problem	
Person's Initials	(b)(6)	Γ
Sex	Male	Γ
Gender	Cisgender man/boy	Γ
Please Specify Other Gender		Г
Age (specify unit of time for age)		Γ
Date of Birth	(b)(6)	Γ
Weight	9.9 kg	Γ
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Asian Vhite Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

None

Please list all allergies (such as to drugs, foods, pollen or others)

None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

He is an infant.

List all current prescription medications and medical devices being used.

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None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
None

Section F - About the Person Fill	ing Out This Form 1 of 1	
Primary?	Yes	Τ
Reporter is Patient?		T
Title		T
Last name	(b)(6)	T
Middle Name		Τ
First name	(h)(c)	T
Number/Street	(b)(6)	T
City		t
State/Province		T
Country	UNITED STATES	T
ZIP or Postal code	$(\mathbf{h})(\mathbf{n})$	T
Telephone number	(b)(6)	t
Email address		T
Fax		T
Reporter Organization		t
Department		t
Reporter Speciality		t
Today's date	11-Dec-2023	t
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2023-91539 | Department: CFSAN | RCT No.: RCT-1187551 | CTU Triage Date: 14-Dec-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	13-Dec-2023	CTU Received Date	13-Dec-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User	User		
User/Group				
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	28-Jul-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident/Please Describe Below)	

any additional documents if necessary)

My 15 month old child was found to have elevated lead levels on testing at her pediatrician's office. Initial lead level was 14.4, it has since been downtrending, but remains elevated. She consumed Wana Bana Apple cinnamon products regularly during the Spring of 2023 prior to this test result.

elevant Test/Laboratory Data			1 of 3
Test Name	LEAD LEVEL	Test Date	28-Jul-2023
Test Result	14.4	Test Unit	
Low Test Range		High Test Range	
More Information Available?		15-	S

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Relevant Test/Laboratory Data		20 ×	2 of 3
Test Name	LEAD LEVEL	Test Date	05-Sep-2023
Test Result	11.4	Test Unit	
Low Test Range		High Test Range	
More Information Available?			
Relevant Test/Laboratory Data		-	3 of 3
Test Name	LEAD LEVEL	Test Date	30-Oct-2023
Test Result	7.1	Test Unit	
Low Test Range		High Test Range	
More Information Available?		5	
Additional Comments			
Section B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
Section C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple Cinnamo	n Fruit Puree	
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Facility	
Strength		If Other	
NDC number		9%	
Did the problem stop after the person reduced the dose or stopped taking or using the product?			

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person started taking or using the product again?	r -			
ug Therapy			1	of 1
Expiration date				
Lot number				
Dosage Form		177	22	
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Oct-2022	20		
Date the person stopped taking or using the product	30-Jun-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?				
hy was the person using the p	roduct? (such as	what condition was it supp	osed to treat) 1 (of 1
for food				
Returned to Manufacturer On				
ction D - About the Medical De	evice			
Name of medical device				
Name of the company that makes the medical device				
	e model, catalog	lot, serial, or UDI number	and the expiration date, if you	
her identifying information (The ate them)				can

Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem occurred?		
For implanted medical devices ONLY (suc	h as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	

Receipt No: RCT-1187551 FDA 3500B Form

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es: 5				

Person's Initials	Unspecified
Sex	Female
Gender	Not selected
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	
Weight	
Ethnicity (Choose only one)	
Race (Check all that apply)	
aco (oncor an mar appiy)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American
known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)
	o drugs, foods, pollen or others)
ise list all allergies (such as t	
ase list all allergies (such as t	o drugs, foods, pollen or others)
ase list all allergies (such as t any other important informati	o drugs, foods, pollen or others)
ase list all allergies (such as t any other important informati	o drugs, foods, pollen or others) on about the person (such as smoking, pregnancy, alcohol use, etc.)

S	Section F - About the Person Filling Out This Form		1 of 1
Г	Primary?	Yes	
Г	Reporter is Patient?		

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Title		Γ
Last name	(b)(6)	Γ
Middle Name		T
First name	(b)(6)	t
Number/Street		t
City		t
State/Province		t
Country	UNITED STATES	t
ZIP or Postal code		T
Telephone number		t
Email address	(b)(6)	ſ
Fax		T
Reporter Organization		T
Department		Γ
Reporter Speciality		Ī
Today's date	13-Dec-2023	Ī
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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CTU No.: FDA-CDER-CTU-2023-93066 | Department: CFSAN | RCT No.: RCT-1189148 | CTU Triage Date: 19-Dec-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	19-Dec-2023	CTU Received Date	19-Dec-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Case	First Name	Last Name	Email Address	Phone	
Reporter	First Name Last Name		Linai Address	Phone	
2	(b)(6)	(b)(6)	(b)(6)	(b)(6)	
ection A	- About the Problem				
	ind of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the o	effect (including new or worsening symptor thich could have or led to a problem quality of the product g from one product maker to another maker		
Date th	e problem occurred	29-Sep-2023			
Serious		No			
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death			

My 2-1/2 year old son tested with lead level of 9.1 on 09/29/23. He had been consuming the WanaBana Cinnamon Applesauce pouches all summer long almost daily. He was retested on 11/6/23 and his lead level went down to a 7.6. He had stopped consuming the WanaBana Applesauce mid August of 2023.

Relevant Test/Labo	ratory Data		1 of 2
Test Name	VENUS BLOOD TEST	Test Date	29-Sep-2023
Test Result	9.1	Test Unit	
Low Test Range		High Test Range	
More Information A	wailable?		

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Relevant Test/Labo	ratory Data		2 of 2
Test Name	VENUE BLOOD TEST	Test Date	06-Nov-2023
Test Result	7.6	Test Unit	
Low Test Range		High Test Range	
More Information A	vailable?		

Additional Comments

Section B - Product Availability Do you still have the product in case we need to evaluate it? No Do you have a picture of the product? (check yes if you are including a picture) No

Section C - About the Products

				1 01 1
Suspect	Yes			
Primary?	Yes	Yes		
Туре	Drug/Biologic	Drug/Biologic		
This report is about	Food/Medical food	1		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Cinnamon Applesauce			
Name of the company that makes (or compounds) the product	WanaBana			
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility		
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Drug Therapy				1 of 1
Expiration date	01-Nov-2023			
Lot number	Unknown			
Dosage Form				
Quantity		If Other		

1 of 1

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Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	15-Mar-2023			
Date the person stopped taking or using the product	15-Aug-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?				
Returned to Manufacturer On				
Section D - About the Medical De	evice			900
Name of medical device				
Name of the company that makes the medical device				
Other identifying information (The ocate them)	e model, catalog, l	ot, serial, or UDI number,	and the expiration da	te, if you can
Model Number				
Model Number Catalog Number				
Catalog Number				
Catalog Number Lot Number				
Catalog Number Lot Number Serial Number				
Catalog Number Lot Number Serial Number UDDI Number				
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem		æmakers, breast implants	, etc.)	

Section E - About the Person	who had the Problem	
Person's Initials	(b)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for ag	3)	
Date of Birth	(b)(6)	

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Weight	13.5 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

N/a

Please list all allergies (such as to drugs, foods, pollen or others)

N/a

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/a

List all current prescription medications and medical devices being used.

None

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Baking soda detox baths Epson salt detox bath Easy ready green gummie vitamins Following cdc guidelines for healthy diet if elevated levels of lead

ection F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	-(D)(O)	
City	_ , , , ,	
State/Province		

CTU No.: FDA-CDER-CTU-2023-93066 | Department: CFSAN | RCT No.: RCT-1189148 | CTU Triage Date: 19-Dec-2023 | Total Pag es: 5

Country	UNITED STATES
ZIP or Postal code	(h)(c)
Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	19-Dec-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Receipt No: RCT-1182393 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Date the person stopped taking or using the product	20-Nov-2023	
Date the person reduced dose of the product	20-Nov-2023	
Give best estimate of duration		
Is therapy still on-going?		
y was the person using the pr	oduct? (such as what	condition was it supposed to treat) 1 of 1
Baby loves this babyfood eat ever	y feeding after breast mill	ĸ
Returned to Manufacturer On		
ction D - About the Medical De	wice	
Name of medical device		
Name of the company that		
makes the medical device		
Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem		
occurred?		
		akers, breast implants, etc.)
occurred?		akers, breast implants, etc.) Date the implant was taken out (If relevant)
occurred? r implanted medical devices O ate the implant was put in	NLY (such as pacema	Date the implant was taken out (If
occurred? r implanted medical devices O ate the implant was put in	NLY (such as pacema	Date the implant was taken out (If
occurred? implanted medical devices O ite the implant was put in ction E - About the Person Wh	NLY (such as pacema no Had the Problem	Date the implant was taken out (If
occurred? implanted medical devices O ite the implant was put in ction E - About the Person Wh Person's Initials	NLY (such as pacema to Had the Problem	Date the implant was taken out (If
occurred? implanted medical devices O ite the implant was put in ction E - About the Person Wh Person's Initials Sex Gender	NLY (such as pacema to Had the Problem (5)(5) Male	Date the implant was taken out (If
occurred? r implanted medical devices O ate the implant was put in ction E - About the Person Wh Person's Initials Sex	NLY (such as pacema to Had the Problem (5)(5) Male	Date the implant was taken out (If

Ethnicity (Choose only one) Race (Check all that apply)

Weight

6.75 kg

Not Hispanic/Latino

American Indian or Alaska Native

Description	B.I.m.	DOT -	1100000	
receipt	INC:	RUI-	1182393	

CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Asian White Black or African American
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) NA
Please list all allergies (such as to drugs, foods, pollen or others) peanut butter
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
List all current prescription medications and medical devices being used. Amoxicilin 400mg Poly-vitamin/w iron solution
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
NA

ection F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	$(l_{2})(\mathbf{C})$	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1182393 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-86494 (Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Γ
Today's date	25-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1182791 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		54		
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	27-Nov-2023	CTU Received Date	27-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Direct			

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	13-Nov-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

My 20 month old son had a Wanabana cinnamon applesauce pouch on 11/13/2023. I didn't see the recall until the next day on the news. It was purchased back in September by my mother-in-law, possibly from Target. He may have had two since they typically come in packs of three and my sister-in-law said she may have been given one for her baby. My son had a lead blood test on 11/16/2023 and the results were 2.1 ug/dL. He had a lead blood test 5 months earlier on 06/01/2023 which was <1.0 ug/dL. We don't have the product. We have a picture of him eating the pouch but it's not clear enough to make out the lot number or exp date.

levant Test/Laborato	ry Data	195	1 of 2
Test Name	LEAD, WHOLE BLOOD	Test Date	01-Jun-2023
Test Result	<1.0	Test Unit	MICROGRAMS PER DEC

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag es: 5

Low Test Range		High Test Range	
More Information Available?			
levant Test/Laboratory Data			2 of 2
Test Name	LEAD, WHOLE BLOOD	Test Date	16-Nov-2023
Test Result	2.1	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	
More Information Available?			
ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wananana Apple Cinnamo	on Fruit Puree	
Name of the company that makes (or compounds) the product	Wanabana		
	Over-the-Counter		
Product Type(check all that apply)	Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility	
	Compounded by a Pharmacy Generic	or an Outsourcing Facility	
apply)	Compounded by a Pharmacy Generic		
apply) Strength	Compounded by a Pharmacy Generic		
apply) Strength NDC number Did the problem stop after the person reduced the dose or stopped taking or using the	Compounded by a Pharmacy Generic Biosimilar		

CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag es: 5

Lot number	
Dosage Form	
Quantity	If Other
Frequency	If Other
How was it taken or used	If Other
Date the person first started taking or using the product	
Date the person stopped taking or using the product	
Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Returned to Manufacturer On	
ection D - About the Medical Dev	ce
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The	model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ocate them)	
2	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
Serial Number UDDI Number	
UDDI Number	
UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	LY (such as pacemakers, breast implants, etc.)

S	Section E - About the Person Who Had the Problem		
Γ	Person's Initials	8085	
	Sex	Male	
	Gender	Not selected	

Receipt No: RCT-1182791 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag es: 5

Please Specify Other Gender		
Age (specify unit of time for age)	20 Month(s)	
Date of Birth		
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag es: 5

Number/Street		
City	(h)(6)	
State/Province	(b)(6)	
Country	UNITED STATES	
ZIP or Postal code		
Telephone number	(h)(G)	
Email address	(b)(6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	27-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Receipt No: RCT-1183168 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	9		
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	28-Nov-2023	CTU Received Date	28-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact		116-	100	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A	- About the Problem	1		
100 CONTRACTOR 100 CONT	nd of problem was it? all that apply)	Used a product incorrectly Noticed a problem with the	e effect (including new or worsening symp which could have or led to a problem quality of the product ng from one product maker to another mai	

	a star beserving more demonstration beserve commenter and the second
Date the problem occurred	28-Nov-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

My son's lead level is elevated after he consumed the cinnamon applesauce pouches from WanaBana.

Relevant Test/Laborato	ry Data		1 of 1
Test Name	LEAD TEST	Test Date	28-Nov-2023
Test Result	8.0	Test Unit	MICROGRAMS PER DEC ILITRE

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

				_	
Low Test Range	0	High Test Range	3.5		
More Information Available?					
ditional Comments	_				
				_	
ction B - Product Availability					
Do you still have the product in	No				
case we need to evaluate it?	-				
Do you have a picture of the	No				
product? (check yes if you are including a picture)					
	1				
ction C - About the Products	i i		10	f1	
Suspect	Yes				
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical fo	od			
Name of the product as it	WanaBana cinn	amon applesauce pouches			
appears on the box, bottle,	1.942.0294.96949.0210				
or package (Include as many					
names as you see)	-				
Name of the company that makes (or compounds) the					
product					
Product Type(check all that	Over-the-Count				
apply)					
	Compounded by a Pharmacy or an Outsourcing Facility				
	Generic				
	Biosimilar				
Strength		If Other			
NDC number	-				
Did the problem stop after the					
person reduced the dose or					
stopped taking or using the product?					
Did the problem return if the					
person started taking or using th	e				
product again?	8				
ug Therapy			1 0	f 1	
Expiration date					
Lot number					
Dosage Form					
Quantity		If Other			
Frequency		If Other			
How was it taken or used		If Other			
Date the person first started	01-Jan-2023	1.0000000			
taking or using the product					

Receipt No: RCT-1183168 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

Date the person stopped taking or using the product	01-Oct-2023	
Date the person reduced dose of the product		
Give best estimate of duration		
Is therapy still on-going?		
Why was the person using the p	roduct? (such as what condition was it supposed to treat)	1 of 1

Returned to Manufacturer On	
ection D - About the Medical Device	
Name of medical device	
Name of the company that makes the medical device	
ther identifying information (The model, on the cate them)	catalog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
UDDI Number Expiration date	
Expiration date Was someone operating the medical device when the problem occurred?	ch as pacemakers, breast implants, etc.)
Expiration date Was someone operating the medical device when the problem	ch as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)

Person's Initials	(8.30)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age))
Date of Birth	(b)(6)
Weight	9.9 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native

Receipt No: RCT-1183168 CTU No.: FDA-CDER-CTU- es: 5	2023-87189 Department: CFSAN RCT No.: RCT-1183168 C	FDA 3500B Form TU Triage Date: 29-Nov-2023 Total Pag
	Asian White Black or African American	
List known medical cor	ditions (Such as diabetes, high blood pressure,	cancer, heart disease, or others)
Please list all allergies	(such as to drugs, foods, pollen or others)	
List any other importan	t information about the person (such as smoking	, pregnancy, alcohol use, etc.)
List all current prescrip	tion medications and medical devices being used	4

List all over-the-counte	r medications and any	vitamins, minerals,	supplements, an	d herbal remedies	beina used.

tion F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(6)(6)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1183168 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		T
Department		Г
Reporter Speciality		Т
Today's date	28-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1183250 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	9						
Company Unit	CDER-CTU	Originating Account	FAERS				
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B				
Priority	Routine	Routine					
Override Auto Calculation Rule	No						
FDA Received Date	29-Nov-2023	CTU Received Date	29-Nov-2023				
CTU Triage Date		CTU Data Entry Date					
Report Type	Spontaneous	Report Classification	Drug				
Assign To	User						
User/Group							
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)					
Case Priority	Direct						

Contact						
Case Reporter	First Name		Last Name	Email Address	Phone	
	(b)(6)		(b)(6)	(b)(6)	(b)(6)	
Section A	- About the P	roblem				
	nd of problem w all that apply)		Used a product incorrectly Noticed a problem with the	e effect (including new or worsening symp which could have or led to a problem quality of the product ng from one product maker to another ma		
Date th	e problem occur		1-Nov-2023			
Serious	6	P	No			
Did any of the following happen? (Check all that apply)			Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			
.Tell us v iny addition	what happene onal documen	d and how i its if necess	t happened (Include ary)	as many details as possible	FDA may reach out to you for	
Daught	er consumed a	recalled prod	uct and lead was found	n her blood - level 7.		

elevant Test/Laboratory Data		5	1 of 1
Test Name	PEDIATRIC LEAD SCREE NING	Test Date	01-Nov-2023
Test Result	7	Test Unit	GRAMS PER DECILITER
Low Test Range	0	High Test Range	3.4
More Information Available?			

Receipt No: RCT-1183250					FDA 35008	B Form	
CTU No. es: 5	FDA-CDER-CTU-2023-87260	Department:	CFSAN RCT No.:	RCT-1183250	CTU Triage Date:	29-Nov-2023	Total Pag

Additional Comments					
Section B - Product Availability					
Do you still have the product in	No				
case we need to evaluate it?	140				
Do you have a picture of the product? (check yes if you are including a picture)	No				
Section C - About the Products				1 of 1	
Suspect	Yes				
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical food				
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Apple Cinnamon P	luree			
Name of the company that makes (or compounds) the product	WanaBana				
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar				
Strength		If Other		-	
NDC number					
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No				
Did the problem return if the person started taking or using the product again?	Doesn't Apply				
Drug Therapy				1 of 1	
Expiration date					
Lot number					
Dosage Form		(c)	2		
Quantity		If Other			
Frequency	Daily	If Other			
How was it taken or used	Oral	If Other			
Date the person first started taking or using the product					
Date the person stopped taking or using the product					
Date the person reduced dose of the product					

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

Give best estimate of duration	2 Month		
Is therapy still on-going?			
hy was the person using the pr	oduct? (such as	what condition was it supposed to treat)	1 of 1
Transition to solid foods			
Returned to Manufacturer On			
action D - About the Medical De	avice		
Name of medical device			
Name of the company that makes the medical device			
cate them)	r model, catalog	, lot, serial, or UDI number, and the expiration date	, ir you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date Was someone operating the medical device when the problem occurred?			
r implanted medical devices O	NLV (such as p	acemakers, breast implants, etc.)	
ate the implant was put in		Date the implant was taken out (If relevant)	
ction E - About the Person Wh	o Had the Probl	em	
	(6008)		
Person's Initials			
Person's Initials Sex	Female		
	Female Cisgender woma	n/girl	
Sex		n/girl	
Sex Gender		n/girl	
Sex Gender Please Specify Other Gender		n/girl	
Sex Gender Please Specify Other Gender Age (specify unit of time for age)	Cisgender woma	n/girl	
Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth	Cisgender woma (b)(6)		

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
Sickle cell trait
Please list all allergies (such as to drugs, foods, pollen or others)
Dairy
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
Baby
List all current prescription medications and medical devices being used.
N/a
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
N/a
2073

Section F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		

Department		Γ
Reporter Speciality		Γ
Today's date	29-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		54			
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	29-Nov-2023	CTU Received Date	29-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)					
Case Priority					

Contact		16				
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		
Section A	- About the Problem					
	ind of problem was it? all that apply)	Used a product incorrectly Noticed a problem with the	e effect (including new or worsening sympt which could have or led to a problem quality of the product ng from one product maker to another make	100.0400.		
Date the problem occurred		06-Nov-2023				
Serious	8	No				
Did any of the following happen? (Check all that apply)		Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Ulfe-threatening Death Other serious/important me	ermanent harm			

any additional documents if necessary)

My son consumed WanaBana Cinnamon Applesauce pouches prior to the recall. After recall notice was released, lead blood test was performed and result was elevated. Only known exposure was the recalled pouches. Plan to retest (via venipuncture, not capillary) at beginning of January 2024 to evaluate if level is still elevated.

evant Test/Laboratory	1 of 1			
Test Name	LEAD, CAPILLARY	Test Date	06-Nov-2023	
Test Result	11	Test Unit	MICROGRAMS PER DEC	
Low Test Range	0	High Test Range	3	

	More Information Available?					
Ac	Iditional Comments					
Se	ction B - Product Availability					
	Do you still have the product in	No				

FDA 3500B Form

Do you have a picture of the No product? (check yes if you are including a picture)	case we need to evaluate it?	No	
	product? (check yes if you are	No	

ection C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical foo	đ	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple	Cinnamon Fruit Puree	
Name of the company that makes (or compounds) the product	WanaBana		
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility	
Strength		If Other	
NDC number		1	
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	e		
rug Therapy			1 of 1
Expiration date			
Lot number			
Dosage Form		22	2
Quantity		If Other	
Frequency		If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	01-Aug-2023		
Date the person stopped taking or using the product	29-Oct-2023		

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
	roduct? (such as what condition was it supposed to treat) 1 of 1
Snack	
Returned to Manufacturer On	
ection D - About the Medical De	avice
Name of medical device	
Name of the company that makes the medical device	
ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
or implanted medical devices C	NLY (such as pacemakers, breast implants, etc.)
ate the implant was put in	Date the implant was taken out (If relevant)
ection E - About the Person Wh Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	10.35 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native

Receipt	Mar	BCT.	1183358	
Neueipi	1 W D	110-1-	1103300	

CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pag es: 5

	White Black or African An	nerican		
List known medical None	conditions (Such as diabetes,	high blood pressure, car	ncer, heart disease, or oth	iers)
Please list all allerg	ies (such as to drugs, foods, po	ollen or others)		
List any other impo	rtant information about the pers	son (such as smoking, p	regnancy, alcohol use, et	c.)
List all current pres	cription medications and medic	al devices being used.		
List all over-the-cou	unter medications and any vitar	nins, minerals, suppleme	ents, and herbal remedies	s being used.

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	$(l_{r})(c)$	
Telephone number	(b)(6)	
Email address		

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	29-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	3	54	1.12 1.12
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	29-Nov-2023	CTU Received Date	29-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact		10		
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	04-Nov-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
ell us what happened and hov additional documents if nece	v it happened (Include as many details as possible FDA may reach out to you fo ssary)

elevated blood lead level of 6.7 on November 7. At his 2 year old screening in March his level was <1. The pouches were purchased and consumed in July, August and September. He did not have any of that brand of pouch in October.

evant Test/Laborato	ry Data		1 of 1
Test Name	BLOOD LEAD LEVEL	Test Date	04-Nov-2023
Test Result	6.7	Test Unit	GRAMS PER DECILITER

CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pag es: 5

Low Test Range		High Test Range		
More Information Available?			-	
Iditional Comments				
ction B - Product Availability				
Do you still have the product in	No			
case we need to evaluate it? Do you have a picture of the	No			
product? (check yes if you are	NO			
including a picture)				
ction C - About the Products	c.			1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it	Cinnamon applesau	08		
appears on the box, bottle,	2002/02/02/04/02/07/00/08			
or package (Include as many names as you see)				
Name of the company that	WanaBana			
makes (or compounds) the product				
Product Type(check all that				
apply)	Over-the-Counter			
		armacy or an Outsourcing Facility		
	Generic			
Strength	Biosimilar	If Other		
NDC number		II Ould		
Did the problem stop after the person reduced the dose or				
stopped taking or using the				
product? Did the problem return if the				
person started taking or using th	e			
product again?				
ug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started	11-Jul-2023			
taking or using the product				

Date the person stopped taking or using the product	28-Sep-2023
Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Thy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
action D - About the Medical De	wice
Name of medical device	
Name of the company that makes the medical device	
ther identifying information (The	a model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	
Construction of the Constr	
Model Number	
Model Number Catalog Number	
Model Number Catalog Number Lot Number	
Model Number Catalog Number Lot Number Serial Number	
Model Number Catalog Number Lot Number Serial Number UDDI Number	
Model Number Catalog Number Lot Number Serial Number	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Τ	Date the	11 C 10 C 10 C 10 C	was	taken	out (If
_	relevant)	1			

Section E - About the Person Who Had the Problem (b)(6) Person's Initials Sex Male Gender Cisgender man/boy Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b)(6) Weight 13.5 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawailan or Other Pacific Islander

Date the implant was put in

Receipt No: RCT-1183426 CTU No.: FDA-CDER-CTU-2023-87451 Department: CFSAN RCT No.: RCT-118: es: 5	FDA 3500B Form 426 CTU Trage Date: 30-Nov-2023 Total Pag
Asian White Black or African American	
List known medical conditions (Such as diabetes, high blood pres	sure, cancer, heart disease, or others)
Please list all allergies (such as to drugs, foods, pollen or others)	
List any other important information about the person (such as sn	noking, pregnancy, alcohol use, etc.)
List all current prescription medications and medical devices bein	g used.
List all over-the-counter medications and any vitamins, minerals,	supplements, and herbal remedies being used
List an over the counter medications and any vitamins, ministrals,	supplements, and neroal remoties being used.

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(6)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(6)(6)	
Telephone number	(b)(6)	
Email address		

Fax		Г
Reporter Organization		Γ
Department		Γ
Reporter Speciality		Г
Today's date	29-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		54		
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	29-Nov-2023	CTU Received Date	29-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	24-Oct-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
 Tell us what happened and how any additional documents if nece 	w it happened (Include as many details as possible FDA may reach out to you for ssary)
Consumed 4 Wanabana cinnamo	n pouches. Confirmed elevated blood lead level.

elevant Test/Laborato	ry Data	10	
Test Name	VENOUS BLOOD LEAD T EST	Test Date	08-Nov-2023
Test Result	13.6	Test Unit	MILLIGRAMS PER DECIL ITRE

CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pag es: 5

Law Test Danse		High Test Danse	S.	
Low Test Range		High Test Range		
More Information Available?				
ditional Comments				
ction B - Product Availability				
Do you still have the product in	No			
case we need to evaluate it?				
Do you have a picture of the product? (check yes if you are	No			
including a picture)				
ction C - About the Products	<u></u>			1 of 1
Suspect	Yes			1011
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
		namen fruit nurse		
Name of the product as it appears on the box, bottle,	WanaBana apple cin	mamon muit puree		
or package (Include as many				
names as you see)				
Name of the company that	WanaBana			
makes (or compounds) the product				
Product Type(check all that	Over-the-Counter			
apply)				
		armacy or an Outsourcing Facility		
	Generic			
Characte	Biosimilar	100		
Strength		If Other		
NDC number				
Did the problem stop after the				
person reduced the dose or stopped taking or using the				
product?				
Did the problem return if the				
person started taking or using the	в			
product again?				1 of 1
ug Therapy				1 01 1
Expiration date				
Lot number	-			
Dosage Form			1	
Quantity	Other	If Other	4 pouches	
Frequency	4 times a day	If Other		
How was it taken or used		If Other	~	
Date the person first started	24-Oct-2023			
taking or using the product				

Receipt No: RCT-1183446 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pag es: 5

Date the person stopped taking	24-Oct-2023	
or using the product		
Date the person reduced dose of the product		
Give best estimate of duration		
Is therapy still on-going?		
y was the person using the pr	roduct? (such as what condition was it supposed to treat) 1	of 1
Returned to Manufacturer On		
tion D - About the Medical De	evice	
Name of medical device		
Name of the company that		
makes the medical device	e model, catalog, lot, serial, or UDI number, and the expiration date, if you	1000
ate them)	e model, catalog, lot, selial, of ODI number, and the expiration date, if you	Can
Model Number		
Model Number Catalog Number Lot Number		
Catalog Number		
Catalog Number Lot Number		
Catalog Number Lot Number Serial Number		
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the		
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem		
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?		
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	ONLY (such as pacemakers, breast implants, etc.)	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?		
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in tion E - About the Person Wit Person's Initials	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem Female	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in tion E - About the Person Wit Person's Initials Sex	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in tion E - About the Person Wit Person's Initials Sex Gender	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem Female Cisgender woman/girl	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in toon E - About the Person Wif Person's Initials Sex Gender Please Specify Other Gender	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem Female Cisgender woman/girl	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in tion E - About the Person Wh Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age)	ONLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem Female Cisgender woman/girl	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? Implanted medical devices O te the implant was put in ton E - About the Person Wif Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem Female Cisgender woman/girl 5 Year(s)	

American Indian or Alaska Native

Race (Check all that apply)

Receipt No: RCT-1183446		FDA 35008	Form
CTU No.: FDA-CDER-CTU-2023-87460 (Department: es: 5	RCT-1183446 CTU Triage Date	30-Nov-2023	Total Pag

	Asian White Black or African American	
List known medic	al conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	

Please list all allergies (such as to drugs, foods, pollen or others)

dairy

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

anemia was diagnosed

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

flintstones multi-vitamins

ction F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province	(b)(6)	
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	29-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	3	54	1.12 1.12
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Nov-2023	CTU Received Date	30-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)			

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	
Serious	No
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)

My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level.

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	
More Information Available?		

Receipt No:	RCT-1183492			FDA 35008	3 Form
CTU No.: es: 5	FDA-CDER-CTU-2023-87513 Department:	CFSAN RCT No.: RCT-1183492	CTU Triage Date:	30-Nov-2023	Total Pag

Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple Cinna	amon Fruit Puree Pouch	185	
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharm Generic Biosimilar	acy or an Outsourcing Facility	ŕ	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?				
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				
Date the person reduced dose of the product				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-87513 | Department: CFSAN | RCT No.: RCT-1183492 | CTU Triage Date: 30-Nov-2023 | Total Pag es: 5

Give best estimate of duration		
Is therapy still on-going?		
	oduct? (such as what co	ndition was it supposed to treat) 1 of 1
Returned to Manufacturer On		
ection D - About the Medical De	vice	
Name of medical device		
Name of the company that makes the medical device		
Other identifying information (The ocate them)	model, catalog, lot, seri	ial, or UDI number, and the expiration date, if you can
Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem occurred?		
or implanted medical devices O	NLY (such as pacemake	ers, breast implants, etc.)
Date the implant was put in		Date the implant was taken out (If relevant)
Section E - About the Person Wh	o Had the Problem	
Person's Initials	000	
Sex	Female	
Gender	Not selected	
Please Specify Other Gender		
Age (specify unit of time for age)	3 Year(s)	
Date of Birth		
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Na Native Hawailan or Other Pac Asian White	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

ection F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code		
Telephone number		
Email address		
Fax		
Reporter Organization		

Department		Γ
Reporter Speciality		Γ
Today's date	30-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	01-Dec-2023	CTU Received Date	01-Dec-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly v	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make	
Date the	e problem occurred	27-Nov-2023		
Serious		Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Blinth defect Life-threatening Death Other serious/important mer	rmanent harm	
incident	erious/important medical t(Please Describe Below)		as many details as possible F	

any additional documents if necessary)

I had fed our two children WanaBana cinnamon applesauce from the Dollar Store for about the last 12 months. The children are ages 5 and 6. They have routine blood work ups and have never had detectable lead levels. Given the newly reported lead reports in this product which I learned about on 11/26, I took both in on Monday the 27th to be tested. Both tested with elevated lead levels. The 5 year old was 6.1 and the 6 year old was 2.6. Reports are available.

evant Test/Laboratory	Data		1 of 1
Test Name	LEAD	Test Date	17-Jan-2019
Test Result	None detected	Test Unit	
Low Test Range		High Test Range	

More Information Available?				
ditional Comments				
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ction C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana			
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facil	ty	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	1			
ig Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other	8	
Date the person first started taking or using the product				
Date the person stopped taking or using the product				

Date the person reduced dose of the product			
Give best estimate of duration			
Is therapy still on-going?			
hy was the person using the p	oduct? (such as what cond	lition was it supposed to treat)	1 of 1
Returned to Manufacturer On			
Returned to Manufacturer On			
ection D - About the Medical De	evice		
Name of medical device			
Name of the company that			
makes the medical device			
ther identifying information (The cate them)	e model, catalog, lot, serial	, or UDI number, and the expiration d	ate, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the			
medical device when the problem occurred?			
r implanted medical devices C		MANONING AN DOLENO MININA PROVINCIAN	
ate the implant was put in		Date the implant was taken out (If relevant)	
ection E - About the Person Wh	None Constant		
Person's Initials	Unspecified		
Sex	Male		
Gender	Cisgender man/boy		
Please Specify Other Gender			
Age (specify unit of time for age)	6 Year(s)		
Date of Birth			
Weight			

American Indian or Alaska Native

Native Hawailan or Other Pacific Islander

Asian

Ethnicity (Choose only one) Race (Check all that apply)

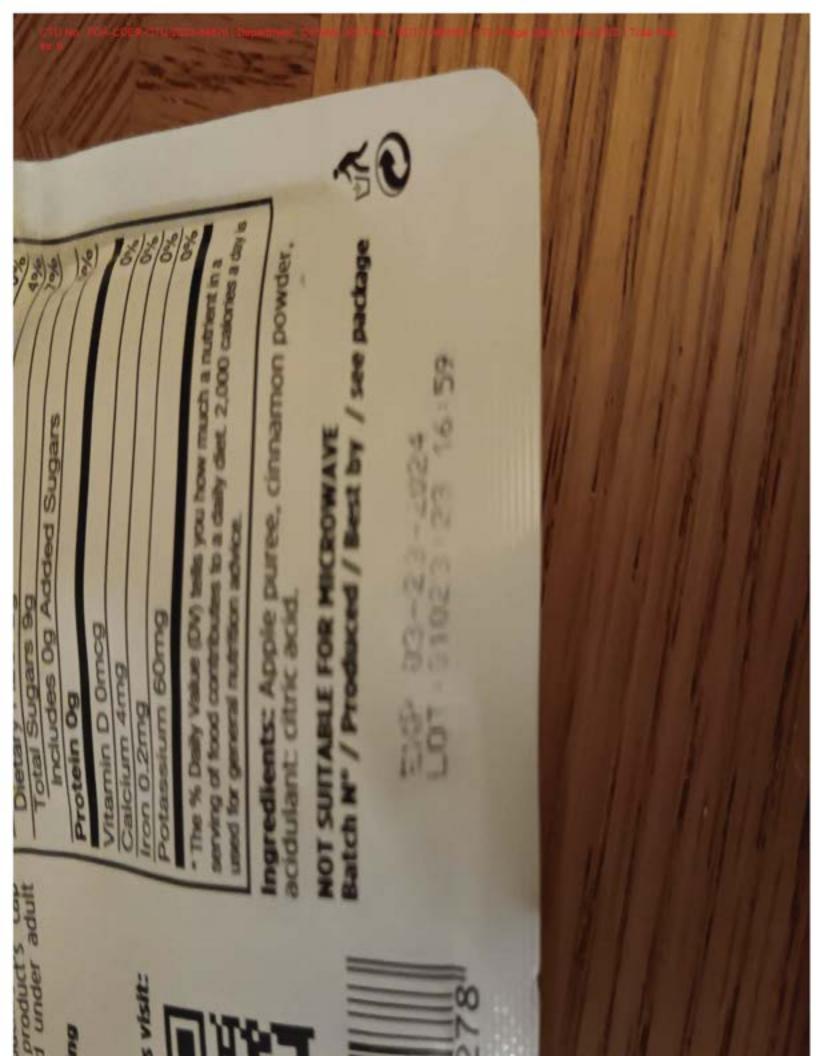
Description DOT 11010	C D
Receipt No: RCT-11842	5.5

CTU No.: FDA-CDER-CTU-2023-88329 | Department: CFSAN | RCT No.: RCT-1184253 | CTU Triage Date: 04-Dec-2023 | Total Pag es: 7

White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Please list all allergies (such as to drugs, foods, pollen or others)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address	$(\sim)(\circ)$	

Fax		
Reporter Organization		
Department		Γ
Reporter Speciality		
Today's date	01-Dec-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	17-Nov-2023	CTU Received Date	17-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact				
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b)(6)
Age	21 Month(s)
Date of Birth	
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Weight	
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Serious	Yes	
Outcome Attributed to Adverse Event (Check all that apply)	Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

FDA 3500 Form

es. 4	Department: CESAN [RCT No	RCT-1180909 CTU Triage Date	17-Nov-2023 Total Pag
	_		
	Congenital Anomaly/Birth Defe		
D. 1 (D 1)	Required Intervention to Prevent Permanent Impairment/Damage		
Date of Death			
Date of Event	25-Oct-2023		
Date of this Report	17-Nov-2023		
scribe Event, Problem or Prod	uct Use Error		
from the Dollar Tree located at eith	Tree around 10/23/23. Moth her (b)(6) in't remember which location e pouches of puree but upon for a blood test. The pediatric	er reports that she purchase she purchased this product hearing the recall information cian's office contacted the he	d a three pouch pack of the produc . Mother states from. Mother can't remember exact on on the news mother contacted with department via phone on
evant Test/Laboratory Data			1 of 1
Test Name	VENOUS BLOOD LEAD T EST	Test Date	08-Nov-2023
Test Result	7.9	Test Unit	MICROGRAMS PER DEC
×		High Test Range	
Low Test Range		High rest Kange	> 3.5 mcg/dL
		nigit restriatige	> 3.5 mcg/dL
Low Test Range More Information Available? ditional Comments		nign rest nange	> 3.5 mcg/dL
More Information Available?	Preexisting Medical Con	d not have an elevated bloo	
More Information Available? Intional Comments Child had previously been tested f er Relevant History, Including No pre-existing health conditions r	Preexisting Medical Con reported by mother.	d not have an elevated bloo	
More Information Available? Information Available? Information Available? Child had previously been tested f er Relevant History, Including No pre-existing health conditions r PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)	Preexisting Medical Con reported by mother.	d not have an elevated bloo	
More Information Available? ditional Comments Child had previously been tested f er Relevant History, Including No pre-existing health conditions r PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on	Preexisting Medical Con reported by mother. No	d not have an elevated bloo	
More Information Available? ditional Comments Child had previously been tested f er Relevant History, Including No pre-existing health conditions r PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)	Preexisting Medical Con reported by mother.	d not have an elevated bloo	
More Information Available? Information Available? Information Available? Information Child had previously been tested f er Relevant History, Including No pre-existing health conditions r PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are	Preexisting Medical Con reported by mother. No	d not have an elevated bloo	

PLITCHER PROTOKLENE CONTRACTOR OF A		
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report involves:	Food/Medical food	
Name, Strength, Manufactur	er/Compounder (from product label)	
Product Name	Wana Bana Apple Cinnamon Fruit Puree	

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 4

Strength	233 G gram(s)	If Other		
Manufacturer/Compounder	Wana Bana			
NDC# or Unique ID				
Product Type(check all that apply)	Compounded Generic Biosimilar			
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			
ıg Therapy		0		1 of 1
Dose or Amount		If Other	-	
Frequency		If Other		2
Route	Oral	If Other	1	
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Lot Number Expiration Date				
				1 of 1
Expiration Date				1 of 1
Expiration Date				1 of 1
Expiration Date gnosis for Use (indication)				1 of 1
Expiration Date Ignosis for Use (indication) SUSPECT MEDICAL DEVICE				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name				1 of 1
Expiration Date gnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name				1 of 1
Expiration Date Ignosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State				1 of 1
Expiration Date gnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model #				1 of 1
Expiration Date gnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog #				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot #				1 of 1
Expiration Date gnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial #				1 of 1
Expiration Date gnosis for Use (Indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date	Health Professional			1 of 1

Receipt No: RCT-1180909 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 4

Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

. REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b)(6)		
Middle Name			
First Name	(b)(6)		
Address	(U)(U)		
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	16110	1	
Phone	(b)(6		
Email		/	
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Nurse	If Other	
Also Reported to	Manufacturer/Com User Facility Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	and the second		

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	19-Nov-2023	CTU Received Date	19-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it?	Were hurt or had a bad side effect (including new or worsening symptoms)	
(Check all that apply)	Used a product incorrectly which could have or led to a problem	
	Noticed a problem with the quality of the product	
	Had problems after switching from one product maker to another maker	
Date the problem occurred	20-Sep-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm	
	Disability or health problem	
	Life-threatening	
	Death	
	Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

WanaBana apple cinnamon fruit pouches: On September 20th at her 2yr old appointment my daughter tested positive for high levels of lead by capillary finger prick with level 21.5. She was retested by venous blood draw on September 28th and still tested positive for high levels of lead with level of 21.0. An abdomen X-ray was done on October 2nd for foreign object containing lead and large amount of stool throughout the colon was found so she was treated for constipation- no foreign object was found. On October 25th she was tested yet again and was positive for high levels of lead; this time her level was 25.4. After hearing that WanaBana fruit pouches was the cause of several other children testing for high levels of lead we concluded this was the reason for the spike in her lead levels. The last time she ate the tainted product was October 19th and she ate 3 of them that day as well as multiple previous days. This was approximately a week before she was tested on October 25th. My husband and I were also tested and our tests came back as normal- we never ate any of the apple pouches. Upon research high levels can cause cognitive impairment, irritability, constipation among other issues including death. This is a serious matter of my young child's health! I can't believe something so toxic that's geared towards babies, toddlers and young children fell through the cracks and now has affected my child and others. My daughter still will have to undergo many tests to check her lead levels because of the tainted product as well as who knows what else she will have to go through because lead effects so many different parts of the body. So sad to lose complete faith in a company that was once my child's favorite snack.

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pag es: 7

ievant Test/Laboratory Data		6	1 of 4
Test Name	LEAD CAPILLARY	Test Date	20-Sep-2023
Test Result	21.5	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	
More Information Available?			
evant Test/Laboratory Data		4	2 of 4
Test Name	LEAD BLOOD VENOUS	Test Date	28-Sep-2023
Test Result	21.0	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	
More Information Available?			
evant Test/Laboratory Data		10	3 of 4
Test Name	XR ABDOMEN	Test Date	02-Oct-2023
Test Result	Large amount of stool thro ughout the colon.	Test Unit	
Low Test Range		High Test Range	
More Information Available?			8
evant Test/Laboratory Data			4 of 4
Test Name	LEAD BLOOD VENOUS	Test Date	25-Oct-2023
Test Result	25.4	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	
More Information Available?			
ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the product? (check yes if you are including a picture)	Yes		
ction C - About the Products			1 of 1
Suspect	Yes		
	Yes		
Primary?	res		
	Drug/Biologic		
Primary?			

Name of the company that makes (or compounds) the product	Wanabana			
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility		
Strength		If Other	8	
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Yes			
g Therapy				1 of 1
Expiration date	30-Mar-2024			
Lot number	01023:30			
Dosage Form				
Quantity	Other	If Other	1 7.50oz	
Frequency	Other	If Other	Every day	
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	10-Oct-2022	0	657	
Date the person stopped taking or using the product	19-Oct-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?	Yes			
y was the person using the pr	oduct? (such as	what condition was it supp	osed to treat)	1 of 1
Hunger/nutrition				

Section D - About the	Section D - About the Medical Device		
Name of medical dev	fice		
Name of the compan makes the medical d			
Other identifying infor locate them)	mation (The model, c	talog, lot, serial, or UDI number, and the expiration date, if you can	

1		
Mode	I Number	
Catak	og Number	
Lot N	umber	
Serial	Number	
UDDI	Number	
Expira	ation date	
Was s medic occur	someone operating the cal device when the problem red?	

For implanted medical devices ONLY (suc	al devices ONLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	

Person's Initials	Avet.	
Sex	Female	
Gender	Cisgender woman/girl	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight	10.8 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

action F - About the Person Fill	ng Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title	Change there	
Last name	b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	D)(O)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	19-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



Nutrition Facts

Duine serving	C
Calories % Daily Value	Value
	0/00
Total Fat 00 Total Fat 00	0/00
Trans Fat 09	0/0
Cholesterol 0mg	0%0
Sodium Omg	4%
otal Carbony and	0/0L
Total Sugars 99	700
Includes 0g Added Sugars	0/0
	%0
Vitamin D 0mcg	%0
Calcium 4mg	%0
Iron U.Zmg	%0

 The % Daily Value (DV) tells you now much a much a day is serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder,

acidulant: citric acid.

NOT SUITABLE FOR MICROWAVE Batch N° / Produced / Best by / see package

LOT: 01023:30 EXP: 03 - 30 - 2024

Receipt No: RCT-1181150 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	57		
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	19-Nov-2023	CTU Received Date	20-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

ection A - About the Problem	
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	23-Aug-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
Tell us what happened and how ny additional documents if nece	w it happened (Include as many details as possible FDA may reach out to you for issary)
08/05/2023. She consumed these blood lead level checked. Her first the same day. To verify accuracy, live in a house built in 1952, so we paint testing came back with few a the lead must have been present negative as well. Everything clicke our local news station. Luckily, ou	onth old), was gifted approximately 6 WanaBana apple cinnamon fruit puree pouches on over the next few weeks. At her 12-month well child check on 08/23/2023, she had her t toe prick (capillary) BLL result was 6.2 ug/dL, and it was confirmed by a second toe prick on , she had a repeat BLL done by venous draw on 08/24/2023, with a result of 6.4 ug/dL. We e assume it was an issue with our home. Our water testing came back negative for lead. Our areas of concern (and most did not have deteriorating paint prior to testing). We assumed in some sort of baby food, or baby toy, as my husband and my own BLL tests came back ad when we saw the recall alert for WanaBana apple cinnamon fruit puree pouches with r daughter seemed asymptomatic during this period of time and we only had a few of

these pouches in our home. Without changing anything, home- or diet-wise, (other than no longer eating these pouches) our daughter's blood lead level has started to decrease. As of 10/30/2023, her blood lead level has dropped to 2.2 ug/dL.

Relevant Test/Laboratory Data

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag es: 5

Test Name	LEAD, BLOOD (PEDS) CA PILLARY (IN-HOUSE)	Test Date	23-Aug-2023		
Test Result	6.2	Test Unit	MICROGRAMS PER DEC		
Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL		
More Information Available?					
evant Test/Laboratory Data			2 of 3		
Test Name	LEAD, BLOOD (PEDS) VE NOUS	Test Date	24-Aug-2023		
Test Result	6.4	Test Unit	MICROGRAMS PER DEC		
Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL		
More Information Available?					
evant Test/Laboratory Data		5	3 of 3		
Test Name	LEAD, BLOOD (PEDS) VE NOUS	Test Date	30-Oct-2023		
Test Result	2.2	Test Unit	MICROGRAMS PER DEC		
Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL		
More Information Available?					
ction B - Product Availability	-				
Do you still have the product in case we need to evaluate it?	No				
Do you have a picture of the product? (check yes if you are including a picture)	No				
tion C - About the Products	e		1 of 1		
Suspect	Yes				
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical food				
Name of the product as it appears on the box, bottle, or package (Include as many					
names as you see)	WanaBana apple cinnamon	fruit puree pouches			
names as you see) Name of the company that makes (or compounds) the product	WanaBana apple cinnamon WanaBana	fruit puree pouches			

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag es: 5

T I				a -
	Generic			
Strength	Biosimilar	If Other		
NDC number		1 5 110		
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?				
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other	6	
Frequency		If Other		
How was it taken or used		If Other	2	0.1
Date the person first started taking or using the product	05-Aug-2023	10.000000	-	
Date the person stopped taking or using the product	01-Sep-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?				
Why was the person using the pr	oduct? (such as	what condition was it supp	osed to treat)	1 of 1
Returned to Manufacturer On				
Section D - About the Medical De	avice			
Name of medical device				
Name of the company that makes the medical device	(15.17 J. 16. 11	an the second of		
Other identifying information (The locate them)	a model, catalog,	lot, serial, or UDI number,	and the expiration date	, if you can
Model Number				
Model Number Catalog Number				
and the second design of the second				
Catalog Number				
Catalog Number Lot Number				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag es: 5

Expiration date			
Was someone operating the medical device when the problem occurred?	n		
For implanted medical devices (ONLY (such as pace	makers, breast implants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person W	ho Had the Problem		
Person's Initials	(b)(6)		Т
Sex	Female		T
Gender	Cisgender woman/gir	d	T
Please Specify Other Gender			T
Age (specify unit of time for age)			T
Date of Birth	(b)(6)		T
Weight			T
Ethnicity (Choose only one)	Not Hispanic/Latino		T
Race (Check all that apply)	American Indian or Ala	her Pacific Islander	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Elevated blood lead level. Plagiocephaly.

Please list all allergies (such as to drugs, foods, pollen or others)

None known.

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

None.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Receipt No: RCT-1181405 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	20-Nov-2023	CTU Received Date	20-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
A. PATIE	NT INFORMATION			
Patient	Identifier (In Confidence)	(b)(6)		
Age		2822347 EV		
Date o	f Birth	(b)(6)		

Sex	Female	
Gender	Not selected	
Please Specify Other Gender		
Weight		
Ethnicity (Check single best answer)	Not Hispanic/Latino	
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander	

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Serious	No	
Outcome Attributed to Adverse Event (Check all that apply)	Death Ulfe Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

Date of Death	Congenital Anomaly/Birth Defection Congenital Anomaly/Birth Defection Required Intervention to Prevent		0
Date of Event	13-Oct-2023		
Date of this Report	20-Nov-2023		
scribe Event, Problem o	r Product Use Error		
pouches from April 2023 th	or Product Use Error: Patient consum rough September 2023. The fruit pot 23 and the blood lead level was eleva	uches were purchased at [
testing was done 10/13/20)ata	009903	1 of 1

Γ	Test Name	VENOUS BLOOD LEAD L EVEL	Test Date	13-Oct-2023
	Test Result	11.3	Test Unit	MICROGRAMS PER DEC
Γ	Low Test Range	0	High Test Range	3.4
Г	More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

PRODUCT AVAILABILITY		
Product Available for Evaluation? (Do not send product to FDA)	No	
Returned to Manufacturer on		
Do you have a picture of the product? (check yes if you are including a picture)	No	

), PRODUCT(S)			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic	1	
This report involves:	Food/Medica	l food	
Name,Strength,Manufacturer/0	Compounder (fr	rom product label)	
Product Name	Wana Bana /	Apple Cinnamon Fruit Puree Pouches	
Strength	-	If Other	
Manufacturer/Compounder	Wana Bana		

Receipt No: RCT-1181405 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

NDC# or Unique ID				
Product Type(check all that apply)	Compounded Generic Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?				
g Therapy		96 -	28	1 of 1
Dose or Amount	180 G gram(s)	If Other		
Frequency	Daily	If Other		
Route	Oral	If Other		
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
			1	
Is therapy still on-going?				

Brand Name		
Common Device Name		
Procode		
Manufacturer Name		
City		
State		
Model #		
Lot #		
Catalog #		
Expiration Date		
Serial #		
Unique Identifier (UDI)#		
Operator of Device	Health Professional	
Other		
If Implanted, Give Date	3	

Receipt No: RCT-1181405 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title	0-00-05522		
Last Name	(b)(6)		
Middle Name	International In		
First Name	(b)(6)		
Address	(D)(D)		
City	· / · /		
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	1-10	1	
Phone	(b)(6		
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Nurse	If Other	
Also Reported to	Manufacturer/Com User Facility Distributor/Importe		
If you do NOT want your identity disclosed to the manufacturer	No		

Receipt No: RCT-1181350 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	20-Nov-2023	CTU Received Date	20-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact		10	102	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

ction A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	13-Oct-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

8 month old female Exposure to lead from now recalled apple cinnamon wana bana pouches. Caused a dip in iron level requiring a supplement.

evant Test/Laboratory	Data	<i>a</i> .	1 of 6
Test Name	LEAD, VENOUS	Test Date	06-Nov-2023
Test Result	10.4	Test Unit	MILLIGRAMS PER DECIL
Low Test Range		High Test Range	

evant Test/Laboratory Data			0.54
and the second			2 011
Test Name	LEAD:6ENOUS	Test Date	14-Nov-2023
Test Result	7	Test Unit	MYLLYGRAMS PER DECY YI'RE
Lof Test Range		High Test Range	
More Yrbrmation Available?		30	21
evant Test/Laboratory Data			3 0 1 1
Test Name	HEMATOCRY	Test Date	14-Nov-2023
Test Result	2816	Test Unit	PERCENT
Lof Test Range		High Test Range	
More Yn brmation Available?			
evant Test/Laboratory Data			4 011
Test Name	HEMATOCRY	Test Date	03-Nov-2023
Test Result	32w	Test Unit	PERCENT
Lof Test Range		High Test Range	
More Yn brmation Available?			
evant Test/Laboratory Data		22	5 0 1 1
Test Name	HEMOGLOBW	Test Date	03-Nov-2023
Test Result	11	Test Unit	GRAMS PER DECYLYTER
Lof Test Range		High Test Range	
More Yrbrmation Available?			
evant Test/Laboratory Data		<i></i>	I 01I
Test Name	HEMOGLOBW	Test Date	14-Nov-2023
Test Result	10/2	Test Unit	GRAMS PER DECYLYTER
Lof Test Range		High Test Range	
More Yrbrmation Available?			

Receipt No: RCT-11, 1350				FDA 3500B Form
CTU No.: FDA-CDER-CTU-2023-85421 es: 5	Department	CFSAN RCT No.	RCT-1181350	CTU Triage Date: 21-Nov-2023 Total Pag

Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic	Drug/Biologic		
This report is about	Food/Medical bod			
Name o1the product as it appears on the bo4xbottlex or package (Ynclude as many names as you see)	Wana bana cinnamon apple puree 3 pack			
Name o1the company that makes (or compounds) the product	Wana bana	Wana bana		
Product Type(check all that apply)	Over-the-Counter	armacy or an Outsourcing Facility		
Strength		YOther		
NDC number				
Did the problem stop a ter the person reduced the dose or stopped taking or using the product?				
Did the problem return i1the person started taking or using the product again?				
rug Therapy				1 011
E4piration date				
Lot number				
Dosage Form				
Vuantity		MOther		
v dannay		in our lot		
Frequency		MOther		
	Oral			
Frequency	Oral 25-Sep-2023	MOther		
Frequency Hof f as it taken or used Date the person 1rst started		MOther		
Frequency Hof f as it taken or used Date the person first started taking or using the product Date the person stopped taking	25-Sep-2023 20-Oct-2023	MOther		
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose o1	25-Sep-2023 20-Oct-2023	MOther		
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Give best estimate of duration Ye therapy still on-going?	25-Sep-2023 20-Oct-2023	MOther MOther		
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Give best estimate of duration	25-Sep-2023 20-Oct-2023	MOther		
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Give best estimate of duration	25-Sep-2023 20-Oct-2023	MOther MOther	osed to treat)	1 011
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Give best estimate of duration Ye therapy still on-going?	25-Sep-2023 20-Oct-2023	MOther MOther	osed to treat)	1 011
Frequency Hof f as it taken or used Date the person 1rst started taking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Give best estimate of duration Ye therapy still on-going?	25-Sep-2023 20-Oct-2023	MOther MOther	osed to treat)	1 011

Section D - About the Medical Device

Name o1medical device

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 5

Name of the company that makes the medical device	
	del, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

Date the implant was put in	Date the implant was taken out (If relevant)

Section E - About the Person W	ho Had the Problem
Person's Initials	(b)(6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	7.65 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native Native Hawailan or Other Pacific Islander Asian White Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Prescription iron supplement started 11/18

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

ction F - About the Person Filli	ing Out This Form 1 of	1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		_
State/Province		
Country	UNITED STATES	_
ZIP or Postal code	$(\mathbf{b})(\mathbf{c})$	
Telephone number	(b)(6)	
Email address		_
Fax		_
Reporter Organization		
Department		
Reporter Speciality		_
Today's date	20-Nov-2023	_
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Receipt No: RCT-1181331 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	20-Nov-2023	CTU Received Date	20-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

A. PATIENT	INFORMATION				
Patient Id	lentifier (In Confidence)	(b)(6)			
Age		21 Month(s)			
Date of B	lirth				
Sex		Male			
Gender		Cisgender mar	n/boy		
Please S	pecify Other Gender				
Weight		10.2 kg			
Ethnicity answer)	(Check single best	Hispanic/Latin	D		
Race (Ch	eck all that apply)	Black or Africa	an or Alaska Native In American an or Other Pacific Islander		

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	Death Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage

FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

	Congenital Anomaly/Birth Defects
Date of Death	The quirte of the version to provers contrained in partment bankage
Date of Event	15-Nov-2023
Date of this Report	20-Nov-2023
cribe Event, Problem o	r Product Use Error
Describe Event, Problem, or part of the recall. he has an	or Product Use Error: Ares ate apple sauce with cinnamon that was made by wanabana and was n elevated lead level

evant Test/Laboratory I	Data		1 of 1
Test Name	LEAD	Test Date	15-Nov-2023
Test Result	10.9	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	9?		
ditional Comments			
venous draw			

Other Relevant History, Including Preexisting Medical Conditions

. PRODUCT AVAILABILITY		
Product Available for Evaluation? (Do not send product to FDA)	No	Γ
Returned to Manufacturer on		Γ
Do you have a picture of the product? (check yes if you are including a picture)	No	Γ

D. PRODUCT(S)		1 of 1	
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report involves:	Food/Medical food		
Name,Strength,Manufactu	rer/Compounder (from product label)		
Product Name	wanabana applesauce with cinnamon		
Strength	If Other		
Manufacturer/Compounde	e		

Generated by: SYSTEM

Receipt No: RCT-1181331 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85414 (Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

NDC# or Unique ID				
Product Type(check all that apply)	OTC Compounded Generic Biosimilar			
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			
ug Therapy		22	10	1 of 1
Dose or Amount		If Other		
Frequency		If Other		
Route		If Other		
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
	1		1	
Is therapy still on-going?				
Is therapy still on-going? Lot Number				

Brand Name		
Common Device Name		
Procode		
Manufacturer Name		
City		
State		
Model #		
Lot #		
Catalog #		
Expiration Date		
Serial #		
Unique Identifier (UDI)#		
Operator of Device	Health Professional	
Other		
If Implanted, Give Date	3	

Receipt No: RCT-1181331 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag es: 4

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

. REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	b)(6)		
Middle Name			
First Name	(b)(6)		
Address	$(\mathbf{D})(\mathbf{O})$		
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	16110	1	
Phone	(b)(6)		
Email		/	
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Physician	If Other	
Also Reported to	Manufacturer/Comp User Facility Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	No		

Receipt No: RCT-1182021 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 6

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	57		
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Nov-2023	CTU Received Date	22-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

ontact					
Case	First Name	La	st Name	Email Address	Phone
Reporter	(b)(6)	(b)	(6)	(b)(6)	(b)(6)
ection A	- About the Prol	blem			
	ind of problem was all that apply)		a product incorrectly ed a problem with the	e effect (including new or worsening syn which could have or led to a problem quality of the product ng from one product maker to another m	
Date th	e problem occurre	d 31-Oct-	2023		
Serious	1	Yes			
(Check	all that apply)		vreatening	ermanent harm	
	erious/important m t(Please Describe	nedical			
	vhat happened a onal documents		ened (Include	as many details as possible	e FDA may reach out to you for
My 5 ye had bee was 12	ear old ate 14 pour en sick, headache, .2.	thes of the wanab stomach ache, ti			are of the recall on Oct 31st. He had him lead tested and his lead
	Test/Laboratory				1 of 1
Test Na	ame	LEAD T	EST	Test Date	31-Oct-2023

Test Result

Low Test Range

12.2

High Test Range

Test Unit

UNKNOWN

Receipt No: RCT-1182021 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

More Information Available?	-				
ditional Comments					
Health department came and we access to any lead paint.	have no other source	of contamination. We live in a	a house built in 2009, he doesn't ha	ve	
ction B - Product Availability					
Do you still have the product in case we need to evaluate it?	Yes				
Do you have a picture of the product? (check yes if you are including a picture)	Yes				
ction C - About the Products			1	of 1	
Suspect	Yes				
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical food				
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wanabana Apple cir	nnamon applesauce pouch			
Name of the company that makes (or compounds) the product	Wanabana	Wanabana			
Product Type(check all that apply)	Compounded by a Pl	harmacy or an Outsourcing Facility			
Strength		If Other			
NDC number					
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No				
Did the problem return if the person started taking or using the product again?	Doesn't Apply e				
ig Therapy			1	of 1	
Expiration date	23-Jun-2024				
Lot number	0402323				
Dosage Form		2			
Quantity	Other	If Other	14 Pouches		
Frequency	Twice a day	If Other			
How was it taken or used	Oral	If Other	8		
Date the person first started taking or using the product	15-Oct-2023				
Date the person stopped taking or using the product	31-Oct-2023				

Receipt No: RCT-1182021 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 6

Date the person reduced dose of the product	31-Oct-2023		
Give best estimate of duration			
Is therapy still on-going?	Yes		
iy was the person using the pr	oduct? (such as wha	t condition was it supposed to tre	eat) 1 of 1
Food he likes to eat			
Returned to Manufacturer On			
ction D - About the Medical De	avice		
Name of medical device			
Name of the company that makes the medical device			
her identifying information (The	e model, catalog, lot,	serial, or UDI number, and the e	xpiration date, if you can
ate them)			
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem			
occurred?			
r implanted medical devices O	NLY (such as pacem	akers, breast implants, etc.)	
ate the implant was put in		Date the implant was taken out relevant)	(If
ction E - About the Person Wh	o Had the Problem		
Person's Initials	(b)(6)		
Sex	Male		
	Cisgender man/boy		
Gender	Cisgender maniboy		
Gender Please Specify Other Gender	Cisgender maniboy		
	Cisgender maniboy		
Please Specify Other Gender	(b)(6)		
Please Specify Other Gender Age (specify unit of time for age)			
Please Specify Other Gender Age (specify unit of time for age) Date of Birth	(b)(6)		

American Indian or Alaska Native

Receip	ot No:	RCT-	1182021	

CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 6

	White Black or African Amer	rican		
List known medical co Autism level 2	onditions (Such as diabetes, hi	igh blood pressure, cano	er, heart disease, or othe	rs)
Please list all allergies None	s (such as to drugs, foods, pol	len or others)		
List any other importa Dev. Delays	ant information about the perso	on (such as smoking, pre	egnancy, alcohol use, etc.))::::::::::::::::::::::::::::::::::::::
List all current prescri Guanfacine	iption medications and medica	l devices being used.		
	ter medications and any vitami	ins, minerals, suppleme	nts, and herbal remedies b	being used.
Polyvisol				

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(6)(6)	
Telephone number	(b)(6)	
Email address		



Receipt No: RCT-1182272 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-80364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	24-Nov-2023	CTU Received Date	24-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

ntact				
se porter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)		(b)(6)
	About the Problem	- d.		
	nd of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the q	effect (including new or worsening sympto hich could have or led to a problem uality of the product g from one product maker to another make	
Date the	problem occurred	19-Nov-2023		
Serious		Yes		
(Check	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med		
	erious/important medical (Please Describe Below)			
	hat happened and how mal documents if neces		is many details as possible F	DA may reach out to you fo
CFSAN Novemb my face	CAERS PHONE REPORT per 19 from Dollar Tree. Im	24-NOV-2023:My name is mediately after, I had a rea perience these symptoms a	(b)(6) . I purchased a War ction. My adverse reaction includ and they are getting worse. This p	

Relevant Test Laboratory Data		1 01 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

Receipt No: RCT-1182272 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Т

More Information Available?	-			
Iditional Comments				
ction B - Product Availability				
Do you still have the product in				
case we need to evaluate it?				
Do you have a picture of the	No			
product? (check yes if you are including a picture)				
ction C - About the Products	-			1 of 1
Suspect	Yes			1011
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical foo			
Name of the product as it	WANABANA APP	PLE CINAMON PAUCH		
appears on the box, bottle, or package (Include as many				
names as you see)				
Name of the company that				
makes (or compounds) the				
product				
Product Type(check all that	Over-the-Counter	80		
apply)	Compounded by	a Pharmacy or an Outsourcing Fac	lity	
	Generic			
	Biosimilar	55	52	
Strength		If Other		
NDC number		*		
Did the problem stop after the				
person reduced the dose or				
stopped taking or using the product?				
Did the problem return if the				
person started taking or using the	e			
product again?	1			
ug Therapy				1 of 1
Expiration date	-			
Lot number				
Dosage Form		22	22	
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started	19-Nov-2023			
taking or using the product	+			
Date the person stopped taking or using the product				

T

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Date the person reduced dose of the product		
Give best estimate of duration		
Is therapy still on-going?		
	oduct? (such as wh	at condition was it supposed to treat) 1 of
Returned to Manufacturer On		
ction D - About the Medical De	avice	
Name of medical device		
Name of the company that		
makes the medical device	a model, estales, lat	t, serial, or UDI number, and the expiration date, if you ca
ate them)	e model, catalog, lot	t, senal, or ODI number, and the expiration date, if you ca
Model Number		
Catalog Number		
Lot Number		
Serial Number		
UDDI Number		
Expiration date		
Was someone operating the		
medical device when the problem		
occurred?		
r implanted medical devices O	NLY (such as pace	makers, breast implants, etc.)
ate the implant was put in		Date the implant was taken out (If
		relevant)
	AND A DESCRIPTION OF A DESCRIPTION	
ction E - About the Person Wh Person's Initials	In Had the Problem	
Sex	Not selected	
Gender	Not selected	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth		
Weight		
and the second se		
Ethnicity (Choose only one)	_	
Race (Check all that apply)	American Indian or Ala	

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White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Please list all allergies (such as to drugs, foods, pollen or others)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	0.063	
Number/Street		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code		
Telephone number	(b)(6)	
Email address		

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Fax		Т
Reporter Organization		Γ
Department		Г
Reporter Speciality		Γ
Today's date	24-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1182375 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	57		
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	25-Nov-2023	CTU Received Date	25-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

	t Name	Last Name	Email Address	Phone
Reporter (b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	15-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
any additional documents if neces	v it happened (Include as many details as possible FDA may reach out to you for ssary) ecause of the Wana Bana applesauce. She's not in any danger, but they are elevated.

Relevant Test/Laboratory Da	ita	8	1 of 1	le :
Test Name	LEAD	Test Date	10-Nov-2023	
Test Result	Slightly elevated	Test Unit		
Low Test Range		High Test Range		
More Information Available?		50		

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ditional Comments				
I don't have a copy of the test, pro and to feed her calcium and retes	atty sure it was in the at in a month.	18 range but don't remember	anything except that it's slightly	elevated
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ction C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cinnamon Applesa	lce		
Name of the company that makes (or compounds) the product	Wana Bana			
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facility		
Strength	tend protection	If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		<i>91</i>	22	
Quantity	Other	If Other	3 Pouch	
Frequency	As needed	If Other		
How was it taken or used	Oral	If Other	2	
Date the person first started taking or using the product				
Date the person stopped taking or using the product				
Date the person reduced dose of the product				

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Give best estimate of duration	3 Month		
Is therapy still on-going?			
/hy was the person using the p	oduct? (such as what cond	dition was it supposed to treat)	1 of 1
Food			
Returned to Manufacturer On			
ection D - About the Medical De	avice		
Name of medical device			
Name of the company that makes the medical device			
ther identifying information (The cate them)	e model, catalog, lot, serial	l, or UDI number, and the expiral	tion date, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
or implanted medical devices C	NLY (such as pacemakers	s, breast implants, etc.)	
ate the implant was put in		Date the implant was taken out (If relevant)	
action E - About the Person Wi	o Had the Problem		
Person's Initials	(b)(6)		
Sex	Female		
Gender	Cisgender woman/girl		
Please Specify Other Gender			
Age (specify unit of time for age)			
Date of Birth	(b)(6)		
Weight	15.75 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Nativ Native Hawailan or Other Pacific Asian White		

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Genetic connective tissue disorder Please list all allergies (such as to drugs, foods, pollen or others) None List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) She ate a "lot" of the applesauce. List all current prescription medications and medical devices being used. Albuterol List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

ection F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		

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Department		Γ
Reporter Speciality		Γ
Today's date	25-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1182388 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	25-Nov-2023	CTU Received Date	25-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	114	110 C	10		
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	27-Oct-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Uife-threatening Death Other serious/important medical incident(Please Describe Below)	

any additional documents if necessary)

child tested for elevated lead levels related to wanabana fruit pouches

evant Test/Laboratory	Data		1 of 2
Test Name	LEAD LEVEL	Test Date	27-Oct-2023
Test Result	6.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.5

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More Information Availabl	e?		
Relevant Test/Laboratory	Data		2 of 2
Test Name	LEAD LEVEL	Test Date	17-Nov-2023
Test Result	4.3	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.5
More Information Availabl	e?	50	
Additional Comments			
lead level improved with n	emoval of WanaBana pouches		

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food	1		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Apple	Wana Bana Apple Cinnamon Fruit Puree		
Name of the company that makes (or compounds) the product	manufactured by - Austrofood			
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility		
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Drug Therapy				1 of 1
Expiration date				
Lot number				

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Quantity If Other Frequency If Other How was it taken or used If Other Date the person first started taking or using the product 01-Jan-2023 Date the person stopped taking or using the product 26-Oct-2023 Date the person reduced dose of the product 6 Date the person reduced dose of the product 1 Is therapy still on-going? 7 /hy was the person using the product? (such as what condition was it supposed to treat) 7 it is a snack for children - in her lunch 8 Returned to Manufacturer On 6 ection D - About the Medical Device 1 Name of medical device 1 Name of the company that 1	Quantity				
How was it taken or used If Other Date the person first started taking or using the product 01-Jan-2023 Date the person stopped taking or using the product 26-Oct-2023 Date the person reduced dose of the product 6 Give best estimate of duration 1s therapy still on-going? hy was the person using the product? (such as what condition was it supposed to treat) it is a snack for children - in her lunch Returned to Manufacturer On ction D - About the Medical Device Name of medical device Name of the company that			If Other		
Date the person first started taking or using the product 01-Jan-2023 Date the person stopped taking or using the product 26-Oct-2023 Date the person reduced dose of the product 26-Oct-2023 Give best estimate of duration 1s therapy still on-going? hy was the person using the product? (such as what condition was it supposed to treat) it is a snack for children - in her lunch Returned to Manufacturer On It is a snack for children - in her lunch Instrument of medical Device Name of medical device Name of the company that It is company that	Frequency		If Other		
taking or using the product 26-Oct-2023 Date the person stopped taking or using the product 26-Oct-2023 Date the person reduced dose of the product 26-Oct-2023 Give best estimate of duration 1 Is therapy still on-going? 1 hy was the person using the product? (such as what condition was it supposed to treat) 1 it is a snack for children - in her lunch 1 Returned to Manufacturer On 1 rction D - About the Medical Device 1 Name of medical device 1 Name of the company that 1	How was it taken or used		If Other		
or using the product		01-Jan-2023			
the product Give best estimate of duration Is therapy still on-going? Is therapy still on-going? hy was the person using the product? (such as what condition was it supposed to treat) It is a snack for children - in her lunch Returned to Manufacturer On It is a snack the Medical Device Name of medical device Name of the company that		26-Oct-2023			
Is therapy still on-going? hy was the person using the product? (such as what condition was it supposed to treat) it is a snack for children - in her lunch Returned to Manufacturer On ction D - About the Medical Device Name of medical device Name of the company that					
Name of medical device Name of the company that	Give best estimate of duration				
hy was the person using the product? (such as what condition was it supposed to treat) It is a snack for children - in her lunch Returned to Manufacturer On ction D - About the Medical Device Name of medical device Name of the company that	s therapy still on-going?				
ction D - About the Medical Device Name of medical device Name of the company that					
Name of medical device Name of the company that	Patiened to Manufactures On				
Name of the company that					
	tion D - About the Medical De	vice			
makes the medical device	tion D - About the Medical De	vice			
ther identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if yo cate them)	tion D - About the Medical De Name of medical device Name of the company that	vice			
	tion D - About the Medical De Name of medical device Name of the company that makes the medical device er identifying information (The	-	ot, serial, or UDI number, a	and the expiration date, if you	can

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical de	evices ONLY (such as pa	acemakers, breast implants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Pe	rson Who Had the Probl	em	
Person's Initials	(b)(6)		

Г	Person's Initials	(b)(6)	Ţ
	Sex	Female	
Γ	Gender	Cisgender woman/girl	
Γ	Please Specify Other Gender		

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Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	12.15 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

none

Please list all allergies (such as to drugs, foods, pollen or others)

none

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

none

List all current prescription medications and medical devices being used.

none

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

none

Section F - About the Per	son Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		

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CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

City	(b)(6)
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	(h)(G)
Email address	(b)(6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	25-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Receipt No: RCT-1182393 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	25-Nov-2023	CTU Received Date	25-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact					
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	16-Nov-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)

I have been feeding my son (b)(6)	WanaBana puree apple sauce for 2 months. I found out the baby food was
recalled 11/24/2023 through my Aunt and grand	mother contacting saying they seen the recall on the news. I've been to the
	kept being sick vomiting, belly aches, irritable 10/16/2023, 11/08/2023, and
	s weight loss. November 16,2023 was his well check with his pediatrician
	me about his Blood work stating he had high levels of lead and prescription
was waiting at the pharmacy in (b)(6)	. I can be reach at (b)(6)

Relevant Test/Laborato	ery Data	π.	1 of 1	
Test Name	CBC(PLATELETS) LEAD BLOOD COMPLETE AS D IRECTED	Test Date	16-Nov-2023	
Test Result		Test Unit		

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CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag es: 5

Low Test Range		High Test Range	Lead poisioning	
More Information Available?				
ditional Comments				
I will be getting his MyChart resu	lts Monday 11/27/202	3 December 13,2023 for lead leve	el check and well check	
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ection C - About the Products			1 of 1	
Suspect	Yes		and a second	
Primary?	Yes	Yes		
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple cinnamon fruit puree pouch			
Name of the company that makes (or compounds) the product	Weis, WanaBana, S	Schnucks		
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facility		
Strength	If Other			
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ug Therapy			1 of 1	
Expiration date	30-Nov-2023			
Lot number				
Dosage Form				
Quantity	Other	If Other	3 pouch	
Frequency	3 times a day	If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	14-Sep-2023			

Receipt No: RCT-1180168 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-84264 | Department: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

More Information Available?				
ditional Comments				
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ction C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			 2
This report is about	Food/Medical food			
Name of the product as it	Apple cinnamon frui	t ouree		
appears on the box, bottle, or package (Include as many names as you see)				
Name of the company that makes (or compounds) the product	Wana bana			
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing	Facility	
Strength		If Other		
NDC number		1		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		22		
Quantity		If Other		
Frequency	Twice a day	If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	20-Oct-2021			
Date the person stopped taking or using the product	07-Nov-2023			

1

Receipt No: RCT-1180168 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-84264 | Department: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Date the person reduced dose of the product		
Give best estimate of duration		
Is therapy still on-going?		
Why was the person using the p	oduct? (such as what condition was it supposed to treat) 1 of 1	
Favorite apple sauce		
Returned to Manufacturer On		Τ
Section D - About the Medical D	vice	
Name of medical device		
Name of the company that makes the medical device		T
Other identifying information (Th locate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can	Ú.
		-
Model Number		+
Catalog Number		+
Lot Number		
Serial Number		1
UDDI Number		
Expiration date		
Was someone operating the medical device when the problem occurred?		
For implanted medical devices 0	NLY (such as pacemakers, breast implants, etc.)	
Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person W	o Had the Problem	
Person's Initials	b)(6)	
Sex	Male	T
Gender	Cisgender man/boy	T
Please Specify Other Gender		T
Age (specify unit of time for age)		T
Date of Birth	(b)(6)	+
Weight	16.65 kg	$^{+}$
Ethnicity (Choose only one)	Not Hispanic/Latino	+

American Indian or Alaska Native

Asian

Race (Check all that apply)

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White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
N/A	
Please list all allergies (such as to drugs, foods, pollen or others)	100
N/A	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used	đ.
Cilantro heavy metal detox	

ction F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		
State/Province	144	
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1180168 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-84264 | Department: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Fax		Т
Reporter Organization		Γ
Department		Г
Reporter Speciality		Γ
Today's date	15-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



nent: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	5		(#
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	Routine	
Override Auto Calculation Rule	No		
FDA Received Date	15-Nov-2023	CTU Received Date	15-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A	- About the Problem			
	tind of problem was it? all that apply)	Used a product incorrectly Noticed a problem with the	te effect (including new or worsening symp which could have or led to a problem a quality of the product ing from one product maker to another ma	PANG PHILE
Date th	ne problem occurred	29-Oct-2023		
Serious	No			
	y of the following happen? all that apply)	Hospitalization - admitted Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important m	emanent harm	
	what happened and how onal documents if neces		as many details as possible	FDA may reach out to you for
My son	has consumed some apple	e puree packages and isr	't feeling too well. Vomiting and h	as since been complaining of

headaches. We checked packaging and it's a product just recalled for lead contamination. Ours matched the names and batch # of contaminated product. He only consumed two boxes of three packets but when tested he is showing elevated lead in his blood.

Test Name	LEAD PANEL	Test Date	09-Nov-2023
Test Result	Positive for lead	Test Unit	
Low Test Range		High Test Range	

Receipt No: RCT-1180289						FDA 3500	B Form
CTU No.: FDA-CDER-CTU-2023-84316 es: 7	Department:	CFSAN	RCT No.:	RCT-1180289	CTU Triage Date:	16-Nov-2023	Total Pag

dditional Comments					
ection B - Product Availability					
Do you still have the product in case we need to evaluate it?	No				
Do you have a picture of the product? (check yes if you are including a picture)	Yes				
ection C - About the Products			1 of 1		
Suspect	Yes			Т	
Primary?	Yes			1	
Туре	Drug/Biologic			T	
This report is about	Food/Medical food				
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cinnamon Apple P	'uree			
Name of the company that makes (or compounds) the product	WanaBana				
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility			
Strength		If Other			
NDC number				1	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No				
Did the problem return if the person started taking or using the product again?					
rug Therapy			1 of 1		
Expiration date	09-Jul-2024				
Lot number	05023:09				
Dosage Form		(c)			
Quantity		If Other			
Frequency	Daily	If Other			
How was it taken or used		If Other			
Date the person first started taking or using the product					
Date the person stopped taking or using the product					
Date the person reduced dose of the product					

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84316 | Department: CFSAN | RCT No.: RCT-1180289 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 7

Give best estimate of duration	
Is therapy still on-going?	
	product? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
Section D - About the Medical D	Device
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (TI	he model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ocate them)	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	m
For implanted medical devices	ONLY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If
	relevant)
Section E - About the Person W	
Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	41.4 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native
	Asian White
	Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Autism Spectrum, ADHD, sensory processing disorder

Please list all allergies (such as to drugs, foods, pollen or others)

Unknown

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

Adderall, Vyvanse, Abilify and Guanfacine

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Persor	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title	and the second second	
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		

Receipt No: RCT-1180289 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-84316 | Department: CFSAN | RCT No.: RCT-1180289 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 7

Department		Γ
Reporter Speciality		Г
Today's date	15-Nov-2023	Г
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

CTU No : FDA-CDER-CTU-2023-84316 | Department: CFSAN | RCT No : RCT-1180289 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 7

> Net Weight: 7.50 oz (213 g)

GINDAGON FRUIT PUREE No preservatives

•Gluten free

:



TETU No FDA-EDER & TV-1926-84316 Department: CESAN RCT No ROT	0%
TURATED FOR FUR STORE SAUGE SAUGE Department CESAN (RCT No. RCT	0%
esterol Omg	0%
0000	4%
Carbohydrate 12g ary Fiber 2g	7%
l Sugars 9g Judes 0g Added Sugars	0%
n 0g	
D Omcg	0%
	0%
n 4mg	0%
mg Jm 60mg	0%

2023 | Total Pag

ly Value (DV) tells you how much a nutrient in a od contributes to a daily diet. 2,000 calories a day is eral nutrition advice.

: Apple puree, cinnamon powder, tric acid.

LE FOR MICROWAVE roduced / Best by / see package

LOT: 05023:09 EXP:07-09-2024

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2		14					
Company Unit	CDER-CTU	Originating Account	FAERS					
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B					
Priority	Routine	Routine						
Override Auto Calculation Rule	No							
FDA Received Date	15-Nov-2023	CTU Received Date	15-Nov-2023					
CTU Triage Date		CTU Data Entry Date						
Report Type	Spontaneous	Report Classification	Drug					
Assign To	User							
User/Group								
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)						
Case Priority	Direct							

ontact			
Case First Name Reporter	Last Name	Email Address	Phone
∠ (b)(6)	(b)(6)	(b)(6)	(b)(6)
ection A - About the Prob	lem		, , , , ,
What kind of problem was (Check all that apply)	Used a product incorrect Noticed a problem with t Had problems after swite	side effect (including new or worsening sym tly which could have or led to a problem the quality of the product ching from one product maker to another m	
Date the problem occurred	i 24-Jul-2023		
Serious	Yes		
Did any of the following ha (Check all that apply)	Required help to preven Disability or health probl Disability or health problem	t permanent harm	
Other serious/important m incident(Please Describe B	edical		
.Tell us what happened a ny additional documents	nd how it happened (Includ if necessary)	le as many details as possible	FDA may reach out to you for
		al levels of lead in her blood. She h	as been more irritable and cranky.
elevant Test/Laboratory I	Data		1 of 1

elevant Test/Laboratory	Data		1 of 1
Test Name	LEAD	Test Date	24-Jul-2023
Test Result	8.2	Test Unit	
Low Test Range		High Test Range	

Receipt No: RCT-1180195 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

More Information Available?					T	
dditional Comments						
					Τ	
ection B - Product Availability					ė	
Do you still have the product in case we need to evaluate it?	No					
Do you have a picture of the product? (check yes if you are including a picture)	No					
ection C - About the Products				1 of 1		
Suspect	Yes				Τ	
Primary?	Yes				1	
Туре	Drug/Biologic				1	
This report is about	Food/Medical food					
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana bana apple o	cinnamon fruit puree				
Name of the company that makes (or compounds) the product	Wana bana	Wana bana				
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Fac	ity			
Strength		If Other			1	
NDC number						
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes					
Did the problem return if the person started taking or using the product again?	Doesn't Apply					
ug Therapy				1 of 1		
Expiration date						
Lot number						
Dosage Form						
Quantity		If Other				
Frequency		If Other				
How was it taken or used		If Other	8			
Date the person first started taking or using the product	07-Oct-2022					
Date the person stopped taking or using the product	15-Feb-2023					

	F
the product Give best estimate of duration	
Is therapy still on-going?	
ny was the person using the p	roduct? (such as what condition was it supposed to treat) 1 of 1
Good pick pouch	
Returned to Manufacturer On	
ction D - About the Medical D	
Name of medical device	
Name of the company that	
makes the medical device	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	le moder, catalog, lot, senal, or obi number, and the expiration date, if you can
Madel Mumber	
Model Number	
Catalog Number	
Catalog Number	
Catalog Number Lot Number Serial Number UDDI Number	
Catalog Number Lot Number Serial Number	
Catalog Number Lot Number Serial Number UDDI Number	n
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	n DNLY (such as pacemakers, breast implants, etc.)
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices C ate the implant was put in	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices C ate the implant was put in	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) ho Had the Problem
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices of ate the implant was put in	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O ate the implant was put in ction E - About the Person Wi Person's Initials	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) ho Had the Problem (b)(6)
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r Implanted medical devices C ate the implant was put in ction E - About the Person WI Person's Initials Sex	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) ho Had the Problem (b)(6) Female
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? In Implanted medical devices O ate the implant was put in Expiration E - About the Person Wi Person's Initials Sex Gender	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) ho Had the Problem (b)(6) Female Cisgender woman/girl
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r Implanted medical devices O ate the implant was put in ection E - About the Person WI Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age)	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) ho Had the Problem (b)(6) Female Cisgender woman/girl

Ethnicity (Choose only one) Race (Check all that apply) Not Hispanic/Latino

Asian

American Indian or Alaska Native

Receipt No:	RCT-1180195							FDA 35008	B Form
CTU No.	FDA-CDER-CTU-2023-84341	Department:	CESAN	RCT No.	RCT-1180195	CTU 1	Triage Date:	16-Nov-2023	Total Pag

es 5

65, 9		
	White Black or African American	
.ist known medical	conditions (Such as diabetes, high b	ood pressure, cancer, heart disease, or others)
lease list all allerg	es (such as to drugs, foods, polien o	r others)
ist any other impo	ant information about the person (su	ich as smoking, pregnancy, alcohol use, etc.)
st all current ores	ription medications and medical devi	ices being used.
ist all over-the-cou	nter medications and any vitamins, n	ninerals, supplements, and herbal remedies being used.

Section F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address	(~)(~)	

Receipt No: RCT-1180195 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Fax		Γ
Reporter Organization		Γ
Department		Γ
Reporter Speciality		Г
Today's date	15-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2		(#)
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	15-Nov-2023	CTU Received Date	15-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct	이번 승규는 것	

ase aporter	First Name	Last Name	Email Address	Phone		
3	(b)(6)	(b)(6)	(b)(6)	(b)(6)		
ction A	- About the Problem					
	tind of problem was it? k all that apply)	Used a product incorrectly Noticed a problem with the	le effect (including new or worsening sympto which could have or led to a problem quality of the product ing from one product maker to another make			
Date th	ne problem occurred	08-Aug-2023				
Seriou	s	Yes				
	y of the following happen? k all that apply)	Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important me	emanent harm			
	serious/important medical ht(Please Describe Below)					

My son was approximately 15 months old when I started to feed my son the wanabana fruit puree pouches. We had the apple cinnamon, banana, pineapple and mango. I brought him to the Dr. For his 1 year wellness check up and his lead level was a 2. I recently had his led levels tested and it is at a 4.5.

Releva	int Test/Laboratory Da	а		1 of 2
Tes	t Name	LEAD	Test Date	11-Nov-2023
Tes	t Result	4	Test Unit	MICROGRAMS PER DEC ILITRE

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84288 | Department: CFSAN | RCT No.: RCT-1180199 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Low Test Range	0.0	High Test Range	3.4
More Information Available?			
evant Test/Laboratory Data			2 of 2
Test Name	LEAD	Test Date	08-Aug-2023
Test Result	2	Test Unit	MICROGRAMS PER DEC
Low Test Range	0.0	High Test Range	3.4
More Information Available?			
ditional Comments			
ction B - Product Availability	T		
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food	d	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wanna bana fruit	puree pouchedis	
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	Compounded by a Generic Biosimilar	Pharmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	в		
Did the problem return if the person started taking or using the product again? ig Therapy	9		1 of 1

Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Feb-2023	1		
Date the person stopped taking or using the product	30-Sep-2023			
Date the person reduced dose of the product				
Give best estimate of duration				
Is therapy still on-going?				
hy was the person using the pr	oduct? (such as wh	at condition was it suppos	ed to treat)	1 of 1
Returned to Manufacturer On				
ection D - About the Medical De	evice			
Name of medical device				
Name of the company that makes the medical device				
ther identifying information (The	e model, catalog, lot	, serial, or UDI number, a	nd the expirat	ion date, if you can
cate them)			19	20 V.
Model Number				
Catalog Number				
Lot Number				
Serial Number				
UDDI Number				
Expiration date				
Was someone operating the medical device when the problem occurred?				
or implanted medical devices O	NLY (such as pacer	nakers, breast implants, e	tc.)	
late the implant was put in		Date the implant was relevant)	Apple Page 1	

S	Section E - About the Person Who Had the Problem		
Γ	Person's Initials	(b)(6)	
	Sex	Male	
Γ	Gender	Not selected	

Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) Asian White Black of African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used.	
Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American indian or Ataska Native American indian or Ataska Native Native Hawaian or Other Pacific Itlander Asian White Units of Atican American Black or Atrican American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all altergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Weight Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American indian or Ataska Native American indian or Ataska Native Native Hawaian or Other Pacific Itlander Asian White Units of Atican American Black or Atrican American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all altergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Race (Check all that apply) American Indian or Alaska Native Native Hawailan or Other Pacific Islander Asian White Black or African American	
Prencent industry of value and industry and industry Asian White Black or African American List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
	1
List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies bein	
) used.
	g used.
	g used.

Section F - About the Pe	rson Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	

CTU No.: FDA-CDER-CTU-2023-84285 | Department: CFSAN | RCT No.: RCT-1180199 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Number/Street	
City	(b)(6)
State/Province	
Country	UNITED STATES
ZIP or Postal code	(h)(c)
Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	15-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pag

MedWatch 3500 Health Professional Report

The FDA Safety Information and Adverse Event Reporting Program

FDA Safety Report ID #	681167	FDA Received Date	15-Nov-2023		
A. PATIENT INFORMATION					
A1. Patient Identifier:		0.00			
A2. Age:		2		Year(z)	
A2. Date of Birth:					
		Male		Yes	
		Female			
A3a. Sex: Enter the patient's s	ex at birth	Undifferentiated		-	
		Decline to answer		2	
		50X)	Cisgender man/boy (gender corresponds with birth sex)		
A3b. Gender: Enter the patient	Gender: Enter the patient's current cender Cisgender woman/girl	Cisgender womanigirl (gende birth sex)	er corresponds with		
		Transgender man/trans man/female-to-male (FTM)			
	Transgender woman/trans woman/ male-to-female (MTF)				
	Other gender category; Please specify;				
		Decline to answer			
A4. Weight:					
A.E. Ethnisibe		Hispanic/Latino			
A5. Ethnicity:		Not Hispanio/Latino		Yes	
		Asian			
		American Indian or Alaskan N	Native		
A6. Race:		Black of African American			
		White		Yes	
		Native Hawaiian or Other Par	cific Islander		

	Advense Event	
B1. Type of Report:	Product Use/Medication Error	
	Product Problem (e.g., defects/malfunctions)	Yes
	Problem with Different Manufacturer of Same Medicine	
	Death (Date of Death)	
	Life-threatening	1.2
	Hospitalization (initial or prolonged)	
	Disability or Permanent Damage	
2. Outcome Attributed to Adverse Event:	Congenital Anomaly/Birth Defects	
	Other Senious or Important Medical Events	Yes
	Required Intervention to Prevent Permanent Impairment/Damage	
33. Date of Event:	25-Oct-2023	
34. Date of this Report:	15 New 2023	

B5. Describe Event, Problem or Product Use/Medication Error:

Child had an elevated blood lead level of 51 per venous draw on 19/25/23. Moher has since called in and stated that the child had been eating the recalled WanaBana Apple Cinnamon Fruit Puree pouches which she had received from a food bank and had also bought from dotter tree. Moher estimates eating up to two to three packs of the fruit puree per day.

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pag

B6. Relevant Tests/Laboratory D	ata:	
Test 1		
Test Date:	25-0x-2023	
	venous lead level	
	- Personal Adda Prov.	
Test Name:		
	91	
and a second		
Test Result.		
Test Unit:	UGOL	
Low Test Range:	0	
High Test Range:		
Test 2		
Test Date:		
Test Name:		
1000 NC		
Test Result:		
Test Unit:		
Low Test Range:		
Low rest Hange.		
High Test Range:		
Test 3		
Test Date:		
Test Name:		
Test Result		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 4		
Test Date:		
Test Name:		
resi name.		
Test Result:		
TOST MEISURE		
Contraction of the Contraction o		
Test Unit:		
Low Test Range:		
High Test Range.		

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pages: 9

B6. Relevant Tests/Laboratory Da	ata:	
Test 5		
Test Date:		
Test Name.		
Test Name.		
Test Result:		
- (1+ (1+ (1+ (1+ (1+ (1+ (1+ (1+ (1+ (1+		
Test Unit:		
Low Test Range:		
High Test Range:		
Test 6		9
Test Date:		
Test Name:		
rest name.		
Test Result:		
Test Unit.		
Low Test Range:		
High Test Range:		
Test 7		
Test Date:		
Test Name:		
Test Result:		
19461196601		
We shall be the		
Test Unit		
Low Test Range:		
High Test Range		
Test 8 Test Date:		
Teor Date.		
0.000		
Test Name:		
Total Date III		
Test Result:		
Test Unit.		
Low Test Range:		
High Test Range:		

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CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 9
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B6. Additional Comments:

Lead level should be 0. Anything 3.5 or higher is considered elevated blood lead level, anything

B7. Other Relevant History, Including Preexisting Medical Conditions:

Have not been able to rule out that the Clevated blood lead level could be environmental. Plan to secheck 3 months from test date to see if lead level decreases since child has stopped eating the appletations

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 9

C. PRODUCT AVAILABILITY	
C1. Product Available for Evaluation?	Ma.
C1. Returned to Manufacturer on:	
C2. Do you have a picture of the product?	

D. SUSPECT PRODUCTS		
Product 1		
D1. This report involves:	Cosmetic	
and a set of the set of the set of the		
	Dietary supplement	
	Food/medical food Other	Yes
D1. Name:	Wanabana Apple Crimamon Fruit Puree pouches	
D1. Strength:		
D1. Manufacturer/Compounder:		100
D1. NDC # or Unique ID:		
D1. Lot #:		5.6
D2. Dose or Amount:		
D2. Frequency:		
D2. Route:		
	Start Stop	Dose Reduced
D3. Treatment Dates/Therapy Dates:	Give best estimate of duration	
	Is therapy still on-going?	
D4. Diagnosis for Use:	ise storagy and on going?	
on ongroup to out.	OTC (Over-the-counter)	
	Compounded	
D5. Product Type:	and the second se	
1 1 1 4 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Generic	
	Biosimilar	
D6. Expiration Date:		4.12
D7. Event Abated After Use Stopped or Dose Reduced?	Doeon't apply	
D8. Event Reappeared After Reintroduction?	Doesn't apply	
Product 2		0.0
D1. This report involves:	Cosmetic	
	Dietary supplement	
	Food/medical food	
-	Other	
D1. Name:		
D1. Strength:		
D1. Manufacturer/Compounder:		
D1. NDC # or Unique ID:		
D1. Lot#:		
D2. Dose or Amount:		
D2. Frequency:		
D2. Route:	0	
Do Transmit Data Theres Data	Start Stop Give best estimate of duration	Dose Reduced
D3. Treatment Dates/Therapy Dates:	Is therapy still on-going?	
	is merapy sur on-going?	
D4. Diagnosis for Use:	AWA (A	
	OTC (Over-the-counter)	
D5. Product Type:	Compounded	
	Generic	
	Biosimilar	
D6. Expiration Date:		
D7. Event Abated After Use Stopped or Dose Reduced?		
D8. Event Reappeared After Reintroduction?		

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pages: 9

E. SUSPECT MEDICAL DEVICE			
E1. Brand Name:	WanaBana Apple Crimamon Fruit Puree p	xches	
E2a. Common Device Name:			
E2b. Procode:			
E3. Manufacturer Name, City and State:			
E4. Model #:			
E4. Catalog #:			
E4. Serial #:			
E4. Lot#:			
E4. Expiration Date: E4. Unique Device Identifier (UDI) #:			
E5. Operator of Device:	Health Professional Patient/Consumer		
E6a. If Implanted, Give Date:	Other		
E6b. If Explanted, Give Date:			
E7a. Is this a single-use device that was reprocessed and reused on a patient?			
E7b. If Yes to Item 7a, Enter Name and Address of Reprocessor:			
E8. Was this device serviced by a third party servicer?			

roduct Name	Therapy Start Date	Therapy End Date
WanaBana Apple Crintamon Fruit Puree pouches		
5		
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6		

CTU No.: FDA-CDER-CTU-2023-84428 | Department: CFSAN | RCT No.: RCT-1180038 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 9

G. REPORTER (b)(6)Last Name First Name Address G1. Name and Address (b)(6) City State/Province/Region ZIP/Postal Code Country US Phone # (b)(6)Email G2. Health Professional? Yei G3. Occupation: Num Manufacturer/Compounder G4. Also Reported To: User Facility Distributer/Importer G5. If you do NOT want your identity disclosed to the No. manufacturer, place an "X" in this box (Confidentiality Requested):

Receipt No: RCT-1180307 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84455 | Department: CFSAN | RCT No.: RCT-1180307 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	16-Nov-2023	CTU Received Date	16-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)			
Section A	- About the Problem					
and the second sec	ind of problem was it? all that apply)	Used a product incorrectly Noticed a problem with the	e effect (including new or worsening symptor which could have or led to a problem quality of the product ng from one product maker to another maker			
Date th	e problem occurred					
Seriou	5	No				
	y of the following happen? all that apply)	Hospitalization - admitted of Required help to prevent pe Disability or health problem Birth defect Life-threatening Death Other serious/important me	ermanent harm			
	what happened and how onal documents if nece	v it happened (Include	as many details as possible F	DA may reach out to you for		
	그는 사람이 다 같은 것 것을 많은 것을 것 같아. 나는 것을 통하는 것이 많이 많이 나라.		ree Pouches over the last several r sults show an elevated level of lea			

levant Test/Laboratory Data			1 of 1
Test Name	LEAD, BLOOD (VENOUS) ARUP	Test Date	06-Nov-2023
Test Result	15.5	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	2 10/00/08

Receipt No: RCT-1180307 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84455 | Department: CFSAN | RCT No.: RCT-1180307 | CTU Triage Date: 16-Nov-2023 | Total Pag

65. 5		
More Information Available?		
Additional Comments		
Section B - Product Availability		
Do you still have the product in case we need to evaluate it?	No	
Do you have a picture of the product? (check yes if you are including a picture)	No	
Section C - About the Products		1 of 1
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report is about	Food/Medical food	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple Cinnamon Fruit Puree	
Name of the company that makes (or compounds) the	Wanabana LLC	

product	
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar
Strength	If Other
NDC number	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	

L.	productr				_
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
E	rug Therapy			1 of 1	
Г	Expiration date				
F	Lot number				
Γ	Dosage Form				
Γ	Quantity		If Other		
Γ	Frequency		If Other		
Γ	How was it taken or used	Oral	If Other		
Γ	Date the person first started taking or using the product	01-Jul-2023			
	Date the person stopped taking or using the product	28-Oct-2023			

Receipt No: RCT-1180307 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84455 | Department: CFSAN | RCT No.: RCT-1180307 | CTU Trage Date: 16-Nov-2023 | Total Pag

es: 5

Date the person reduced dose of the product	28-Oct-2023
Give best estimate of duration	
Is therapy still on-going?	
iy was the person using the pi	roduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
ction D - About the Medical D	avice
Name of medical device	
Name of the company that makes the medical device	
her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
and an	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
r implanted medical devices C	NLY (such as pacemakers, breast implants, etc.)
te the implant was put in	Date the implant was taken out (If
	relevant)
tion E - About the Person Wh	o Had the Problem
Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	congentate managery
Age (specify unit of time for age)	4.5 Year(s)
Date of Birth	
Weight	17.55 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	
riave (oneon an orac approv)	American Indian or Alaska Native

Receipt No: RCT-1180 CTU No: FDA-CDE es: 5	0307 R-CTU-2023-84455 Department: CFSAN RCT No.: RCT-118030	FDA 3500B Form 7 CTU Triage Date: 16-Nov-2023 Total Pag
	White Black or African American	
List known medica	al conditions (Such as diabetes, high blood pressu	ure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

ction F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province	0.05	
Country	UNITED STATES	
ZIP or Postal code		
Telephone number		
Email address	(b)(6)	

Receipt No: RCT-1180307 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84455 | Department: CFSAN | RCT No.: RCT-1180307 | CTU Triage Date: 16-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Γ
Reporter Speciality		Г
Today's date	16-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1180627 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84712 | Department: CFSAN | RCT No.: RCT-1180627 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		54	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	16-Nov-2023	CTU Received Date	16-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact	Contact						
Case Reporter	First Name	Last Name	Email Address	Phone			
	(b)(6)	(b)(6)	(b)(6)	(b)(6)			

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product	
Date the problem occurred	Had problems after switching from one product maker to another maker 20-Oct-2023	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Uife-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)	en een mindele erste de kerste de menske kerste de skriver ook met de skriver.	

On October 19th 2023 my mother (grandmother of those affected) purchased WanaBana Cinnamon fruit puree at a Dollar Tree in (b)(6) The pouches purchased were from LOT 02023:18 15:13, which are listed on the recall. My sons ages 2.5 years and 15 months both ingested only 2 pouches each of the fruit puree pouches between 10/20/2023 and 10/24/2023. Both of my children have previously been tested for lead at their regular check ups with undetectable results. After seeing the recall of these fruit puree pouches I immediately had them tested for lead at their pediatrician. Both of their test results came back with elevated levels of lead in their blood. Our pediatrician has referred us to a specialist at a lead clinic with (b)(6) We are also seeking legal counsel to review and develop a path forward if they are to have any medical problems from this in the future.

Relevant Test/Laboratory Data					
Test Name	LEAD	Test Date	31-Oct-2023		

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84712 | Department: CFSAN | RCT No.: RCT-1180627 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

Test Result	4	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	
More Information Available?			
ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products	,		1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple (Cinnamon fruit puree	
Name of the company that makes (or compounds) the product	WanaBana		
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
ig Therapy			1 of 1
Expiration date	18-Apr-2024		
Lot number	02023:18 15:13		
Dosage Form			
Oursetite	Other	If Other	2 Pouches
Quantity	127.22220	10/2015/51/6	
Frequency		If Other	

Receipt No: RCT-1180627 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84712 | Department: CFSAN | RCT No.: RCT-1180627 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

www.com.theo.com.com.units.co.theo.com	roduct? (such as what condition was it supposed to treat)	1 of 1
Is therapy still on-going?		
Give best estimate of duration		
Date the person reduced dose of the product		
Date the person stopped taking or using the product	24-Oct-2023	
Date the person first started taking or using the product	20-Oct-2023	

Returned to Manufacturer On

action D - About the Medical De	vice
Name of medical device	
Name of the company that makes the medical device	
ther identifying information (The cate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate triesin)	
Madel Montheast	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
Serial Number UDDI Number	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)
Date the implant was put in
Date the implant was taken out (If
relevant)

Section E - About the Person W	/ho Had the Problem	
Person's Initials	(b)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for age		
Date of Birth	(b)(6)	
Weight	12.6 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	

Receipt No: RCT-1180627					B Form
CTU No.: FDA-CDER-CTU-2023-84712 Department: es: 5	CESAN RCT No.	RCT-1180627	CTU Triage Date:	17-Nov-2023	Total Pag

Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
-----------------------------	--	--

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Probiotic, Vitamin C, Childrens multivitamin

Section F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84712 | Department: CFSAN | RCT No.: RCT-1180627 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	16-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1180625 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84710 | Department: CFSAN | RCT No.: RCT-1180625 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			12
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	16-Nov-2023	CTU Received Date	16-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

e First Name orter	Last Name	Email Address	Phone	
(b)(6)	(b)(6)	(b)(6)	(b)(6)	
ction A - About the Problem				
What kind of problem was it? (Check all that apply)	Used a product incorrectly v	e effect (including new or worsening sympto which could have or led to a problem quality of the product ng from one product maker to another make		
Date the problem occurred	20-Oct-2023			
Serious	Yes	Yes		
Did any of the following happen (Check all that apply)	Required help to prevent pe Disability or health problem Birth defect Ulfe-threatening Death	ermanent harm		
Other serious/important medical incident(Please Describe Below				

any additional documents if necessary)

On October 19th 2023 my mother (grandmother of those affected) purchased WanaBana Cinnamon fruit puree at a Dollar Tree in (b)(6) The pouches purchased were from LOT 02023:18 15:13, which are listed on the recall. My sons ages 2.5 years and 15 months both ingested only 2 pouches each of the fruit puree pouches between 10/20/2023 and 10/24/2023. Both of my children have previously been tested for lead at their regular check ups with undetectable results. After seeing the recall of these fruit puree pouches I immediately had them tested for lead at their pediatrician. Both of their test results came back with elevated levels of lead in their blood. Our pediatrician has referred us to a specialist at a lead clinic with (b)(6) We are also seeking legal counsel to review and develop a path forward if they are to have any medical problems from this in the future.

Relevant Test/Laborator	ry Data	34	1 of 1
Test Name	LEAD	Test Date	31-Oct-2023

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84710 | Department: CFSAN | RCT No.: RCT-1180625 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

Test Result	5	Test Unit	MICROGRAMS PER DEC	
Low Test Range	0	High Test Range		
More Information Available?				
ditional Comments				
ction B - Product Availability	_			
Do you still have the product in	Yes			
case we need to evaluate it?	100			
Do you have a picture of the	No			
product? (check yes if you are including a picture)				
ction C - About the Products			1 of 1	
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it	WanaBana Apple (Cinnamon fruit puree		
appears on the box, bottle,				
or package (Include as many names as you see)				
Name of the company that	WanaBana			
makes (or compounds) the product				
Product Type(check all that	Over-the-Counter			
apply)		Pharmacy or an Outsourcing Facility		
	Generic	namacy or an oversourcing racing		
	Biosimilar			
Strength		If Other		
NDC number				
Did the problem stop after the				
person reduced the dose or stopped taking or using the				
product?				
Did the problem return if the	Doesn't Apply			
person started taking or using the product again?				
ig Therapy	-		1 of 1	
Expiration date	18-Apr-2024			
Lot number	02023:18 15:13			
Dosage Form				
Quantity	Other	If Other	2 Pouches	
Frequency		If Other		
requercy		- THE CONTRACTOR		

Receipt No: RCT-1180625 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-84710 | Department: CFSAN | RCT No.: RCT-1180625 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

	roduct? (such as what condition was it supposed to treat)	1 of 1
Is therapy still on-going?	Yes	
Give best estimate of duration		
Date the person reduced dose of the product		
Date the person stopped taking or using the product	24-Oct-2023	
Date the person first started taking or using the product	20-Oct-2023	

Returned to Manufacturer On

ection D - About the Medical De	svice
Name of medical device	
Name of the company that makes the medical device	
ther identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)
Date the implant was put in
Date the implant was taken out (If
relevant)

Section E - About the Person W	ho Had the Problem	
Person's Initials	(b)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight	15.75 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	

Receipt No:	RCT-1180625				FDA 35008	B Form
CTU No. es: 5	FDA-CDER-CTU-2023-84710 Department	CESAN RCT No.	RCT-1180625	CTU Triage Date:	17-Nov-2023	Total Pag

Race (Check all that apply)	American Indian or Alaska Native Native Hawailan or Other Pacific Islander Aslan White Black or African American	
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List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Probiotic, Vitamin C, Childrens multivitamin

ection F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(6)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-84710 | Department: CFSAN | RCT No.: RCT-1180625 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	16-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Receipt No: RCT-1180808 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-84876 | Department: CFSAN | RCT No.: RCT-1180808 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 6

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	-			
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	17-Nov-2023	CTU Received Date	17-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b)(6)
Age	13 Month(s)
Date of Birth	
Sex	Male
Gender	Not selected
Please Specify Other Gender	
Weight	
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Serious	Yes	
Outcome Attributed to Adverse Event (Check all that apply)		

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-84876 | Department: CFSAN | RCT No.: RCT-1180808 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 6

Date of Death	Required Intervention to Prevent Permanent Impairment/Damage	
Date of Event	10-Nov-2023	
Date of this Report	17-Nov-2023	

Describe Event, Problem, or Product Use Error: Patient consumed a product (Wana Bana) that was recalled for elevated levels of lead. Once patients mother found out about the recall and they had some of the recalled product lot number 01023:23 she had scheduled an appointment to get lead levels tested. The patients lead levels were elevated at 6.4 ug/dl. Patient will be getting re-tested in 2-4 weeks to ensure that the levels are back down.

Test Name	LEAD BLOOD (PEDIATRI C) VENOUS	Test Date	10-Nov-2023
Test Result	6.4	Test Unit	MICROGRAMS PER DEC
Low Test Range	0.0	High Test Range	3.4
More Information Available?			
ditional Comments			

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY		
Product Available for Evaluation? (Do not send product to FDA)	/es	
Returned to Manufacturer on		
Do you have a picture of the product? (check yes if you are including a picture)	/es	

D. PRODUCT(S)			1 of 1					
Suspect	Yes	es						
Primary?	Yes	/es						
Туре	Drug/Biologic	Drug/Biologic						
This report involves:	Food/Medical	Food/Medical food						
lame,Strength,Manufacturer/0	Compounder (fr	om product label)						
Product Name	Wana Bana A	pple Cinnamon Fruit Puree Pouches						
Strength	12	If Other	-					
Manufacturer/Compounder	Wana Bana-A	Wana Bana-Austrofood						

Receipt No: RCT-1180808 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-84876 | Department: CFSAN | RCT No.: RCT-1180808 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 5

NDC# or Unique ID				
Product Type(check all that apply)	Compounded Generic Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?				
Drug Therapy		22		1 of 1
Dose or Amount		If Other		
Frequency	Other	If Other	Whenever	
Route		If Other		
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
Is therapy still on-going?	No			
Lot Number	01023:23			
Expiration Date	23-Mar-2024			
Diagnosis for Use (indication)				1 of 1
Was a food product (snack) So gi	ven when patient wa	nted it.		

SUSPECT MEDICAL DEV	ICE	
Brand Name		
Common Device Name		
Procode		
Manufacturer Name		
City		
State		
Model #		
Lot #		
Catalog #		
Expiration Date		
Serial #		
Unique Identifier (UDI)#		
Operator of Device	Health Professional Patient/Consumer Other	
Other		
If Implanted, Give Date		

Receipt No: RCT-1180808 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-84876 | Department: CFSAN | RCT No.: RCT-1180808 | CTU Triage Date: 17-Nov-2023 | Total Pag es: 6

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b)(6)		
Middle Name			
First Name	(h)(6)		
Address	(b)(6)		
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(h)(G)		
Phone	(b)(6)_		
Email	· / /		
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Other Health Professional	If Other	
Also Reported to	Manufacturer/Compoun	der	
If you do NOT want your identity disclosed to the manufacturer	No		

An Grant product To COL An Grant Languer V Chi (For), Outlo Econdra and ISA, DY: Wanabaro and ISA, LLC 2115 W. nabana USA, LLC 2115 W. nabana USA, LLC 2115 W. nabana USA, LLC 2115 W. aga-272-7184 88-272-7184 0052-8PM-AN-0818 OCUP I (The

ol dry place. Once or gerate and min 5 days. COUCH & Sert.

package has a product's cap ed under adult Provide of ĥ Suprision.

· Bilfree Pack Iging · Gates Free · Inside to cal nore products visit:





ENP 03-22-024

~0

2	1 pourof (71g)	50	% Daily Value-	0%	10	10	0%0	4%6	464		and alle		O%	25	ero and	20	rou how much a nutrient in a daily diet. 2,000 calories a dei is on the second	Apple puree, cinnamon powder, ric acid.	AVE / see package
Nutrition Facts	1 Serving Size: Serving Size:	Amount per serving Calories		Total Fat 0g	Saturated Fat 0g	Trans Fat 0g Cholesterol 0mg	Sodium Omg	Total Carbohydrate 129	Dietary Fiber 29	Total Sugars 9g	Includes 0g Added Sugars	Protein 0g	Vitamin D Omeg	Calcium 4mg	Iron 0.2mg	Potassium 60mg	 The % Daily Value (DV) tells you how mu serving of food contributes to a daily diet. 	Ingredients: Apple puree, caridulant: citric acid.	NOT SUITABLE FOR MICROWAVI Batch Nº / Produced / Best by

Receipt No: RCT-1177845 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-81881 | Department: CFSAN | RCT No.: RCT-1177845 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

More Information Available?								
dditional Comments								
ction B - Product Availability								
Do you still have the product in case we need to evaluate it?	No							
Do you have a picture of the product? (check yes if you are	No							
including a picture)								
ction C - About the Products				1 of 1				
Suspect	Yes							
Primary?	Yes							
Туре	Drug/Biologic							
This report is about	Food/Medical food							
Name of the product as it	Wana Bana apple :	sauce pouches						
appears on the box, bottle, or package (Include as many								
names as you see)								
Name of the company that	Wana bana							
makes (or compounds) the product								
Product Type(check all that	Over-the-Counter							
apply)		Pharmacy or an Outsourcing Facility						
	Generic	mannacy or an outsourcing Pacing						
	Biosimilar							
Strength		If Other						
NDC number								
Did the problem stop after the								
person reduced the dose or								
stopped taking or using the product?								
Did the problem return if the	Doesn't Apply							
person started taking or using the								
product again? ug Therapy				1 of 1				
Expiration date	1			1011				
Lot number								
Dosage Form								
Quantity		If Other						
Frequency		If Other						
How was it taken or used	If Other							
Date the person first started	01-Sep-2022	in contra	8					
taking or using the product	01-000-2022							
Date the person stopped taking or using the product	06-Nov-2023							

Receipt No: RCT-1177845 CTU No.: FDA-CDER-CTU-2023-81881 | Department: CFSAN | RCT No.: RCT-1177845 | CTU Triage Date: 07-Nov-2023 | Total Pag

es; 5

Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Why was the person using the p	roduct? (such as what condition was it supposed to treat) 1 of 1
To eat	
Returned to Manufacturer On	
Section D - About the Medical D	evine
Name of medical device	
Name of the company that	
makes the medical device	
Other identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ocate them)	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices C	NLY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If relevant)
Section E - About the Person Wh	ho Had the Problem
Person's Initials	(b)(6)
Sex	Male
Gender	Not selected
Please Specify Other Gender	
Age (specify unit of time for age)	2 Year(s)
Date of Birth	
Weight	10.8 kg
Ethnicity (Choose only one)	Not Hispanic/Latino

American Indian or Alaska Native Native Hawailan or Other Pacific Islander Asian

Race (Check all that apply)

FDA 3500B Form

Receipt No: RCT-1177845					FDA 35008	B Form
CTU No.: FDA-CDER-CTU-2023-81881	Department:	CFSAN RCT No.:	RCT-1177845	CTU Triage Date:	07-Nov-2023	Total Pag

ction F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1177845 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81881 | Department: CFSAN | RCT No.: RCT-1177845 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Γ
Today's date	06-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	5		14		
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	07-Nov-2023	CTU Received Date	07-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct				

Contact	1.		MT-	84	
Case Reporter	First Name	Last Name	Email Address	Phone	ļ
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	03-Nov-2023	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)	an a	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Our daughter was born on (b)(6) . We purchased Wana Bana cinnamon apple baby purée from Dollar Tree in September 2023. Our infant ate approximately 12 packets. We have extra packets she has not eaten at home. We saw the recall for Wana Bana apple cinnamon baby October 30, 2023 for high levels of lead. We were seen by our pediatrician on October 31, 2023. Had blood drawn for lead. Received results from Pediatrician on 11/3/2023 with serum lead results at 20.4 mcg/dL. She has been referred to Hematology. She was also placed on an iron supplement in the meantime.

evant Test/Laborato	ry Data		1 of 1
Test Name	SERUM LEAD	Test Date	31-Oct-2023
Test Result	20.4 mcg/dL	Test Unit	UNKNOWN

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82274 | Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pag es: 7

		Contraction and the first states of	
Low Test Range		High Test Range	
More Information Available?			
Iditional Comments			
ction B - Product Availability			
Do you still have the product in	Yes		
case we need to evaluate it?			
Do you have a picture of the	Yes		
product? (check yes if you are including a picture)			
ction C - About the Products	è.		1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food	1	
Name of the product as it	Wana Bana Aople	Cinnamon Fruit Purée	
appears on the box, bottle,	Trana bana rippio		
or package (Include as many			
names as you see)			
Name of the company that	Wana Bana		
makes (or compounds) the product			
Product Type(check all that			
apply)	Over-the-Counter		
	Compounded by a	Pharmacy or an Outsourcing Facility	
	Generic		
	Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the			
person reduced the dose or			
stopped taking or using the			
product?			
Did the problem return if the			
person started taking or using th product again?	8		
rug Therapy	-		1 of 1
Expiration date	26-Jun-2024		
	-		
Lot number	04023:26		
Dosage Form		10 pc acc 10 / 0	
Quantity	-	If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started			
taking or using the product			

Receipt No: RCT-1178180 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-82274 (Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pag es: 7

		_
Date the person stopped taking or using the product		
Date the person reduced dose of the product		
Give best estimate of duration	1 Month	
Is therapy still on-going?		
ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of	1
Baby food		
Returned to Manufacturer On		_
ction D - About the Medical De	evice	
Name of medical device		
Name of the company that		
makes the medical device		
ate them)		
Model Number		
Model Number Catalog Number		
Model Number Catalog Number Lot Number		
Model Number Catalog Number Lot Number Serial Number		
Model Number Catalog Number Lot Number Serial Number UDDI Number		
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date		
Catalog Number Lot Number Serial Number UDDI Number		
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	NLY (such as pacemakers, breast implants, etc.)	
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?		
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O ate the implant was put in	INLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?	INLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O ate the implant was put in ction E - About the Person Wh	NLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem	
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? If implanted medical devices O ate the implant was put in Ction E - About the Person Wh Person's Initials	NLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant) no Had the Problem	

		4
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight	7.65 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

Receipt No: RCT-1178180 CTU No: FDA-CDER-CTU-2023-82274 (Depar es: 7	FDA 3500B Form tment: CFSAN RCT No.: RCT-1178180 CTU Triage Date: 08-Nov-2023 Total Pag
	slan Ihite Iack or African American
List known medical conditions (Such a None prior to discovery of high lead leve	as diabetes, high blood pressure, cancer, heart disease, or others)
Please list all allergies (such as to dru	gs, foods, pollen or others)
None	
List any other important information at	bout the person (such as smoking, pregnancy, alcohol use, etc.)
List all current prescription medication	s and medical devices being used.
List all over-the-counter medications a	nd any vitamins, minerals, supplements, and herbal remedies being used.
Poly Vi Sol multivitamin	
Section F - About the Person Filling O	ut This Form 1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	(0)(0)	
City	()()	
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1178180 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-82274 (Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pag es: 7

Fax		
Reporter Organization		
Department		Γ
Reporter Speciality		
Today's date	07-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

1 Serving per package Serving Size:	1 pouch (71
Amount per serving	
Calories	50
	% Daily Valu
Total Fat 0g	0
Saturated Fat 0g	0
Trans Fat Og	
Cholesterol Omg	0'
Sodium Omg	0'
Total Carbohydrate 12g	4
Dietary Fiber 2g	7
Total Sugars 9g	
Includes Og Added Sugars	0'
Protein Og	
Vitamin D Omcg	0
Calcium 4mg	0
Iron 0.2mg	0
Potassium 60mg	0

 The % Daily Value (DV) tails you how much a numeric in a serving of food contributes to a daily det. 2,000 calories a day is used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder, acidulant: citric acid.

NOT SUITABLE FOR MICROWAVE Batch N* / Produced / Best by / see package

chuten free

E

N

LOT: 04023:26 EXP:06-26-2024





Kanafactured by AUSTROFOOD SASS Av. God. Emiquer V Gencuchi (Esq.). Outo Eritador: Wanabana USA bit. Wanaban-U. Nanabana USA ULI 2115 W. Streft - Bocsonville R 32209. Inc. 889-272-784 In CIBE 0052-89M-AN-0818 Inc. BER 2557.

ne col dy place. Once net objecate and one within 5 days.

sea his package has a sea his product's cap sea pered under adult

> in hotaging min

han made whit



Nutrition Facts	
1 Serving per puckage Serving Size: 1 p Amount per serving	ouch (71g
Galories	50
×	Cally Value" CVS CVS
Total Fat 0g	CK.
Seturated Fat Og	15
Trans Fat Og	
Cholesterol Omg	15
Sodium Omg	05
Total Carbohydrate 12g	45
Dietary Fiber 2g	175
Total Sugars 9g	- Person
Includes Og Added Sugars	15
Protein Og	11.10
	14
Vitamin D Omog	M
Calcium 4mg	0%
Iron 0.2mg	15
Potassium 60mg	1.0
	-Hirdha

"The % Dely Value (DA) left you how much a name bat serving of local contributes to a daily det. 2,000 colores via a used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder, acidulant, citric acid.

NOT SUITABLE FOR MICROWAVE Batch Nº / Produced / Best by / see package

> EXP: 04-26-2024 LOT: 04123-26 16:32

U

KOSHER

GAR

Net Weight: 2.50 0Z (719)

ADDED



All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2		14
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Nov-2023	CTU Received Date	08-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact					
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		

Patient Identifier (In Confidence)		
Age	28 Month(s)	
Date of Birth		
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Weight	13.2 kg	
Ethnicity (Check single best answer)	Not Hispanic/Latino	
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawalian or Other Pacific Islander	

в	ADVERSE EVENT, PRODUC	CT PROBLEM	
	Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Г	Serious	Yes	
	Outcome Attributed to Adverse Event (Check all that apply)	Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-82538 | Department: CFSAN | RCT No.: RCT-1178375 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 4

Date of Event 01-Nov-2023 Date of this Report 08-Nov-2023 escribe Event, Problem or Product Use Error Describe Event, Problem or Product Use Error	Date of Death	Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage
scribe Event, Problem or Product Use Error	Date of Event	01-Nov-2023
	Date of this Report	08-Nov-2023
Describe Event, Provient, or Product use Enor. Patient ingested 3rd pouches or Wana bana apple null pures. He tested for a	The second	or Product Use Error or Product Use Error: Patient ingested 3-4 pouches of Wana Bana apple fruit puree. He tested for a

evant Test/Laboratory Data			1 of 1
Test Name	VENOUS BLOOD LEAD	Test Date	01-Nov-2023
Test Result	8.1	Test Unit	MICROGRAMS PER DEC
Low Test Range	<3.4	High Test Range	
More Information Available?			
litional Comments			
	Low Test Range More Information Available?	Test Result 8.1 Low Test Range <3.4 More Information Available?	Test Result 8.1 Test Unit Low Test Range <3.4 High Test Range More Information Available?

Other Relevant History, Including Preexisting Medical Conditions

С	PRODUCT AVAILABILITY		 B
Γ	Product Available for Evaluation? (Do not send product to FDA)	ło	
Г	Returned to Manufacturer on		Ţ
	Do you have a picture of the product? (check yes if you are including a picture)	lo	

D. PRODUCT(S)		1 of 1
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report involves:	Food/Medical food	
Name,Strength,Manufactu	rer/Compounder (from product label)	
Product Name	Wana Bana	
Strength	If Other	
Manufacturer/Compounde	e l	

Receipt No: RCT-1178375 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-82538 | Department: CFSAN | RCT No.: RCT-1178375 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 4

NDC# or Unique ID				
Product Type(check all that apply)	OTC Compounded Generic Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?	Doesn't Apply			
ig Therapy		97	10	1 of 1
Dose or Amount		If Other		
Frequency		If Other		
Route		If Other		
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
An even single and the series have a distinguishing a series of the				
Is therapy still on-going?				
Is therapy still on-going? Lot Number				

E. SUSPECT MEDICAL DEV	ICE	
Brand Name		Т
Common Device Name		Г
Procode		Т
Manufacturer Name		Γ
City		Τ
State		Г
Model #		Г
Lot #		Τ
Catalog #		Τ
Expiration Date	2	Т
Serial #		Т
Unique Identifier (UDI)#		Τ
Operator of Device	Health Professional Patient/Consumer	
Other		Γ
If Implanted, Give Date	2	T

Receipt No: RCT-1178375 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-82538 | Department: CFSAN | RCT No.: RCT-1178375 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 4

If Explanted, Give Date	Γ
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

. REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title	0.000		
Last Name	(b)(6)		
Middle Name			
First Name	1->//	21	
Address	(b)(6)		
City		<i>,</i>	
State/Province/Region		'	
Country	UNITED STATES	If Other	
ZIP/Postal Code	(h)(C)	2 2	
Phone	(b)(6)		
Email	$(\sim)(\sim)$		
Fax			
Reporter Organization			
Department			
Reporter Speciality			2
Health Professional?	Yes		
Occupation	Physician	If Other	
Also Reported to	Manufacturer/Comp User Facility Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	No		

Basic Details	2		(#
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Nov-2023	CTU Received Date	08-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

ase eporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
action A	- About the Problem			
	ind of problem was it? all that apply)	Used a product incorrectly	e effect (including new or worsening symp which could have or led to a problem quality of the product ng from one product maker to another mak	
Date th	e problem occurred	07-Nov-2023		
Serious	3	Yes		
(Check	v of the following happen all that apply)	Required help to prevent p Disability or health problem Birth defect Ulfe-threatening Death Other serious/important me	ermanent harm	
	erious/important medica t(Please Describe Below			
Fell us v y additio	vhat happened and h onal documents if neo	ow it happened (Include cessary)	as many details as possible	FDA may reach out to you f
	dler had a wanabana ap st & his tests came back		lay it hit national news that they w	vere recalled. I took him in to get

elevant Test/Laborato	ry Data	1 of 1	
Test Name	LEAD TEST	Test Date	07-Nov-2023
Test Result	6.1	Test Unit	MILLIGRAMS PER DECIL ITRE

Receipt No: RCT-1178434

CTU No.: FDA-CDER-CTU-2023-82566 | Department: CFSAN | RCT No.: RCT-1178434 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 6

Low Test Range		High Test Range			
More Information Available?					
ditional Comments					
ction B - Product Availability					
Do you still have the product in case we need to evaluate it?	No				
Do you have a picture of the	Yes				
product? (check yes if you are including a picture)					
ction C - About the Products				1 of 1	
Suspect	Yes			100 Call 10 Call	
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical food				
Name of the product as it	Wana Bana Mango	o & Banana			
appears on the box, bottle,	1.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5.5				
or package (Include as many names as you see)					
Name of the company that	Wana Bana				
makes (or compounds) the product					
Product Type(check all that	Over-the-Counter				
apply)					
		Pharmacy or an Outsourcing Facility			
	Generic				
	Biosimilar	101			
Strength		If Other			
NDC number	-				
Did the problem stop after the					
person reduced the dose or stopped taking or using the					
product?					
Did the problem return if the					
person started taking or using the	э				
product again? Ig Therapy				1 of 1	
				1011	
Expiration date					
Dosage Form		If Other			
Quantity					
Frequency		If Other			
How was it taken or used		If Other			
Date the person first started taking or using the product					

Receipt No: RCT-1178434 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-82566 | Department: CFSAN | RCT No.: RCT-1178434 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 5

Date the person stopped taking	
or using the product	
Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Why was the person using the p	oduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
Section D - About the Medical De	evice
Name of medical device	
Name of the company that	
makes the medical device	
Other identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
locate them)	

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken ou

Date the	implant	was	taken	out	(If
relevant)					

Section E - About the Person W	ho Had the Problem
Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	1 Year(s)
Date of Birth	
Weight	9.45 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native

es: 6	
	Asian White Black or African American
t known medical conditio	ons (Such as diabetes, high blood pressure, cancer, heart disease, or others)
ase list all allergies (suc	h as to drugs, foods, pollen or others)
any other important infe	amatian about the norman (such as amatian meanages, atabat use, ata)
any other important into	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)
t all current prescription	medications and medical devices being used.
t all current prescription	medications and medical devices being used.
all current prescription	medications and medical devices being used.
	medications and medical devices being used. edications and any vitamins, minerals, supplements, and herbal remedies being used.
all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being used
all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being used
all over-the-counter me tion F - About the Perso Primary?	edications and any vitamins, minerals, supplements, and herbal remedies being used
all over-the-counter me tion F - About the Perso Primary? Reporter is Patient?	edications and any vitamins, minerals, supplements, and herbal remedies being used
all over-the-counter me tion F - About the Perso Primary? Reporter is Patient? Title	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes
all over-the-counter me tion F - About the Perso Primary? Reporter is Patient? Title Last name	edications and any vitamins, minerals, supplements, and herbal remedies being used
all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6)
all over-the-counter me tion F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6)
all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes
all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6)
all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6) (b)(6)
t all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	adications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6) (b)(6) UNITED STATES
all over-the-counter me ction F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	adications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6) (b)(6) UNITED STATES
all over-the-counter me tion F - About the Perso Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	edications and any vitamins, minerals, supplements, and herbal remedies being used on Filling Out This Form 1 of 1 Yes (b)(6) (b)(6)

Receipt No: RCT-1178434 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-82566 | Department: CFSAN | RCT No.: RCT-1178434 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Γ
Reporter Speciality		Γ
Today's date	08-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



Basic Details	25		14
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	10-Nov-2023	CTU Received Date	10-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact	35	900	20-	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	03-Nov-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
ell us what happened and hov additional documents if nece	v it happened (Include as many details as possible FDA may reach out to you f ssary)
My daughter consumed Wana Ba	na pouches from February 2023 until the date of the recall. Her bloodwork indicates a lead were normal at her one year check up. The only thing that has changed about her diet or

E	elevant Test/Laborato	ry Data		1 of 1
	Test Name	LEAD VENOUS	Test Date	03-Nov-2023
	Test Result	7.4	Test Unit	MICROGRAMS PER DEC ILITRE

Receipt No: RCT-1179141

CTU No.: FDA-CDER-CTU-2023-83196 | Department: CFSAN | RCT No.: RCT-1179141 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

Low Test Range		High Test Range	
More Information Available?			
ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Apple (Cinnamon Fruit Puree	
Name of the company that makes (or compounds) the product	Austrofood SAS		
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			
ig Therapy			1 of 1
Expiration date			
Lot number	01023:23		
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started	26-Feb-2023		
taking or using the product	1993-1997-1976-19		

Receipt No: RCT-1179141 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83196 | Department: CFSAN | RCT No.: RCT-1179141 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

	Date the person stopped taking or using the product	27-Oct-2023		
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?			Γ
W	hy was the person using the pr	oduct? (such as what condition was it supposed to treat)	1 of 1	
	Nutrition, not for medical condition	treatment		

Section D - About the Medical Dev	ice
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The locate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)
Date the implant was put in
Date the implant was taken out

Date	the	implant	was	taken	out	(If
releva	ant)					

Section E - About the Person W	ection E - About the Person Who Had the Problem	
Person's Initials	(b)(6)	
Sex	Female	
Gender	Cisgender woman/girl	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

eceipt No: RCT-1179141 CTU No: FDA-CDER-CTU-2023 es: 5	FDA 3500B Form -83196 Department: CFSAN RCT No.: RCT-1179141 CTU Triage Date: 13-Nov-2023 Total Pag
	Asian White Black or African American
ist known medical conditio	ons (Such as diabetes, high blood pressure, cancer, heart disease, or others)
lease list all allergies (suc	ch as to drugs, foods, pollen or others)
ist any other important inf	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)
ist all current prescription	medications and medical devices being used.
st all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being used.
ection F - About the Pers	on Filling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b)(6)
Middle Name	
First name	
Number/Street	
City	-(D)(D)
	(b)(6)
State/Province	
State/Province Country	UNITED STATES
State/Province Country ZIP or Postal code	UNITED STATES
State/Province Country	

Receipt No: RCT-1179141 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83196 | Department: CFSAN | RCT No.: RCT-1179141 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	10-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Basic Details	12		(G
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	11-Nov-2023	CTU Received Date	11-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	ontact				
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

Patient Identifier (In Confidence)	Unspecified
Age	
Date of Birth	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Weight	11.7 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawalian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Serious	Yes	
Outcome Attributed to Adverse Event (Check all that apply)	Death Ulfe Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

Receipt No: RCT-1179210

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-83256 | Department: CFSAN | RCT No.: RCT-1179210 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 4

	Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	01-Nov-2023
Date of this Report	11-Nov-2023
escribe Event, Problem o	Product Use Error
	er Product Use Error: Ingestion of WanaBana cinnamon applesauce. Was given a box for Halloweer nily hearing about recall. Had appointment in clinic on 11-9-23. Lab draw for lead level. Was < 3.4)

Relevant Test/Laboratory D	ata		1 of 1
Test Name	LEAD, BLOOD	Test Date	09-Nov-2023
Test Result	6.7	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	3.4
More Information Available?	2		
Additional Comments	10		and the second

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY		
Product Available for Evaluation? (Do not send product to FDA)	No	
Returned to Manufacturer on		Γ
Do you have a picture of the product? (check yes if you are including a picture)	No	

D. PRODUCT(S)		1 of 1
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report involves:	Food/Medical food	
Name,Strength,Manufactu	rer/Compounder (from product label)	
Product Name	WanaBana Cinnamon Applesauce	
Strength	If Other	
Manufacturer/Compounde	e	

Generated by: SYSTEM

Receipt No: RCT-1179210 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-83256 | Department: CFSAN | RCT No.: RCT-1179210 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 4

NDC# or Unique ID			
Product Type(check all that apply)	OTC Compounded Generic Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			
Drug Therapy			1 of 1
Dose or Amount		If Other	
Frequency		If Other	
Route	Oral	If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			
Diagnosis for Use (indication)			1 of 1

Brand Name		
Common Device Name		
Procode		
Manufacturer Name		
City		
State		
Model #		
Lot #		
Catalog #		
Expiration Date		
Serial #		
Unique Identifier (UDI)#		
Operator of Device	Health Professional	
Other		
If Implanted, Give Date	3	

Receipt No: RCT-1179210 FDA 3500 Form CTU No.: FDA-CDER-CTU-2023-83256 | Department: CFSAN | RCT No.: RCT-1179210 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 4

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

3. REPORTER			1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	^{b)(6)} (b)(6)		
Middle Name			
First Name	(h)(G)		
Address	(D)(O)		
City	· / /-		
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(h)(C)		
Phone	(b)(6)		
Email	$(\sim)(\sim)$		
Fax			
Reporter Organization			
Department			
Reporter Speciality			2.
Health Professional?	Yes		
Occupation	Nurse Practitioner	If Other	
Also Reported to	Manufacturer/Comp		
If you do NOT want your identity disclosed to the manufacturer	No		

Basic Details	2		(#	
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	13-Nov-2023	CTU Received Date	13-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Priority	Direct			

Contact	25	alle.	211	7.1
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	16-Jun-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Ulfe-threatening Death Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

2 year old had elevated blood lead levels resulted in eating Wana Bana fruit pouches, which recently came out in the news as having been tested high for lead.

levant Test/Laboratory	Data		1 of 2
Test Name	LEAD, BLOOD	Test Date	16-Jun-2023
Test Result	8.6	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	

Receipt No: RCT-1179311 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83362 | Department: CFSAN | RCT No.: RCT-1179311 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

More Information Available?			
levant Test/Laboratory Data			2 of 2
Test Name	LEAD, BLOOD	Test Date	28-Sep-2023
Test Result	1.9	Test Unit	MICROGRAMS PER LITE
Low Test Range		High Test Range	
More Information Available?		50	
ditional Comments			
Lead level went down after having) my child refrain from e	eating these fruit pouches (about	a month and a half later).
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic	Drug/Biologic	
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana fruit pouc	hes	
Name of the company that makes (or compounds) the product	Wana Bana		
Product Type(check all that apply)	Over-the-Counter	macy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		
ug Therapy			1 of 1
Expiration date			
Lot number			

Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Aug-2022	20		
Date the person stopped taking or using the product	07-Aug-2023			
Date the person reduced dose of the product				
Give best estimate of duration				0
Is therapy still on-going?				
ny was the person using the pr		1	and the second se	1 of 1

Returned to Manufacturer On

vice
model, catalog, lot, serial, or UDI number, and the expiration date, if you can

Date th	e implant	was pu	ut in
---------	-----------	--------	-------

Date the implant was taken out (If relevant)

Section E - A	ection E - About the Person Who Had the Problem		
Person's Ir	itials (b)(6	5)	
Sex	Male		
Gender	Cisg	ander man/boy	
Please Spi	ecify Other Gender		

Receipt No: RCT-1179311 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83362 | Department: CFSAN | RCT No.: RCT-1179311 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

Age (specify unit of time for age)	2 Year(s)	
Date of Birth		
Weight	17.1 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Per	son Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		

CTU No.: FDA-CDER-CTU-2023-83362 | Department: CFSAN | RCT No.: RCT-1179311 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

City	b)(6)
State/Province	5)(0)
Country	UNITED STATES
ZIP or Postal code	(h)(c)
Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	13-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Basic Details	2		(#
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	13-Nov-2023	CTU Received Date	13-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product
Date the problem occurred	Had problems after switching from one product maker to another maker 24-Mar-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Ufe-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

with his poisoning. The DOH was contacted to check our house for possible exposure to which they did not find a plausible source. After I stopped giving my son these pouches his levels continued to drop over the next 6 months until reaching undetectable levels.

evant Test/Laborato	ry Data	12.	1 of 1
Test Name	VENOUS LEAD TEST	Test Date	22-Mar-2023
Test Result	13	Test Unit	MICROGRAMS PER MIL

Receipt No: RCT-1179339

CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

Low Test Range	0	High Test Range	Indefinite
More Information Available?			
tional Comments			
ion B - Product Availability			
Do you still have the product in	No		
case we need to evaluate it?	4.6		
Do you have a picture of the product? (check yes if you are	No		
ncluding a picture)			
ion C - About the Products			1 of
Suspect	Yes		10537
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food	1	
Name of the product as it	apple cinnamon fr		
appears on the box, bottle,			
or package (Include as many			
names as you see)	West Press		
Name of the company that makes (or compounds) the	WanaBana		
product			
Product Type(check all that	Over-the-Counter		
apply)		Pharmacy or an Outsourcing Facility	
	Generic	Filamacy of an Outsourcing Facility	
	Biosimilar		
Strength	Biosimiar	If Other	1
NDC number			
Did the problem stop after the	Yes		
person reduced the dose or	100		
stopped taking or using the			
product?			
Did the problem return if the person started taking or using the	Doesn't Apply		
product again?			
Therapy			1 of
Expiration date			
ot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
YOW Was it taken or used			

Receipt No: RCT-1179339 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

2 Month
oduct? (such as what condition was it supposed to treat) 1 of 1
avice
1108
e model, catalog, lot, serial, or UDI number, and the expiration date, if you can

Person's Initials	(b)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for age)	12 Month(s)	
Date of Birth		
Weight	7.65 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native	

relevant)

Celpt No: RCT-1179339 CTU No.: FDA-CDER-CTU-2023-83387 es: 5	FDA 3 Department: CFSAN RCT No.: RCT-1179339 CTU Triage Date: 13-Nov-2	3500B Form 2023 Total Pag
	Asian White Black or African American	
st known medical conditions (Su	ich as diabetes, high blood pressure, cancer, heart dise	ase, or others)
lease list all allergies (such as to	drugs, foods, pollen or others)	
ist any other important information	on about the person (such as smoking, pregnancy, alcot	iol use, etc.)
ist all current prescription medic	ations and medical devices being used.	
st all over-the-counter medication	ons and any vitamins, minerals, supplements, and herba	I remedies being used.
ection F - About the Person Filli		1 of 1
Primary?	Yes	

1	
Reporter is Patient?	
Title	
Last name	(b)(6)
Middle Name	
First name	(h)(6)
Number/Street	(b)(6)
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(h)(c)
Telephone number	(b)(6)
Email address	

Receipt No: RCT-1179339 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	13-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Basic Details	12		(#		
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	13-Nov-2023	CTU Received Date	13-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct				

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		
Section /	A - About the Problem					
	kind of problem was it? k all that apply)	Used a product incorrectly Noticed a problem with the	te effect (including new or worsening sympt which could have or led to a problem e quality of the product ing from one product maker to another mak			
Date t	the problem occurred	06-Oct-2023				
Serio	us	No				
(Chec	ny of the following happen? k all that apply)		ermanent harm h edical incident(Please Describe Below)			
any addi	tional documents if nece	ssary)	as many details as possible I	FDA may reach out to you for		
recall are th	we were going through all th	e avenues of what may h	ave caused it to happen. After the b. They have all been tossed now a	recall we found out that those		

levant Test/Laboratory Data			1 of 1
Test Name	LEAD (VENOUS)	Test Date	06-Oct-2023
Test Result	4.2	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.5
More Information Available?			

Receipt No: RCT-1179621 FDA 3500B Fo				B Form		
CTU No.: FDA-CDER-CTU-2023-83651 es: 5	Department:	CFSAN RCT No.	RCT-1179621	CTU Triage Date	14-Nov-2023	Total Pag

dditional Comments				
ection B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ection C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			- /
This report is about	Food/Medical food			1
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple ci	nnamon fruit puree pouches	I.	
Name of the company that makes (or compounds) the product	WanaBana			
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facility		
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
)rug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		22	2	
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				
Date the person reduced dose of the product				

Receipt No: RCT-1179621

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-83651 | Department: CFSAN | RCT No.: RCT-1179621 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

Give best estimate of duration	4 Month
Is therapy still on-going?	
	oduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
ection D - About the Medical De	vice
Name of medical device	
Name of the company that makes the medical device	model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	model, excludy, let, senar, or obt number, and the expiration date, if yes ear
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)
ate the implant was put in	Date the implant was taken out (If relevant)
ection E - About the Person Wh	o Had the Problem
	(b)(6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	
	(b)(6)
Weight	9.045 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	American Indian or Alaska Native

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person F	illing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	$(\mathbf{n})(\mathbf{n})$	
City	(b)(6)	
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		
Fax		
Reporter Organization		1

Receipt No: RCT-1179621 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-83651 | Department: CFSAN | RCT No.: RCT-1179621 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

Department		Γ
Reporter Speciality		Γ
Today's date	13-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Basic Details	2		14
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	14-Nov-2023	CTU Received Date	14-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact			
Case First Name Reporter	Last Name	Email Address	Phone
(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A - About the Problem			
What kind of problem was it? (Check all that apply)	Used a product incorrectly Noticed a problem with the	te effect (including new or worsening sympl which could have or led to a problem e quality of the product ing from one product maker to another maker	
Date the problem occurred	09-Nov-2023		
Serious	Yes		
Did any of the following happen? (Check all that apply)	Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important me	ermanent harm	
Other serious/important medical incident(Please Describe Below)			
 Tell us what happened and ho any additional documents if nece 	w it happened (Include ssary)	as many details as possible	FDA may reach out to you for
	A REAL PROPERTY OF A DESCRIPTION OF A DE	s lead levels were 13 on a lead te	st.
Relevant Test/Laboratory Data			1 of 1

levant Test/Laboratory	Data		1 of 1
Test Name	WHOLE BLOOD LEAD	Test Date	09-Nov-2023
Test Result	13	Test Unit	UNITS PER MILLILITRE
Low Test Range	0	High Test Range	3

Receipt No: RCT-1179805 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

More Information Available?				
dditional Comments				
Pediatrician notified my wife and	I of the results.			
ection B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ection C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			-
Туре	Drug/Biologic			2
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple C	linnamon		
Name of the company that makes (or compounds) the product	WanaBana			
Product Type(check all that apply)	Over-the-Counter	harmacy or an Outsourcing Facilit	Ŷ	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	e			
rug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		2	~	
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	28-May-2023			
Date the person stopped taking or using the product	04-Nov-2023			ļ,

Receipt No: RCT-1179805

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

Date the person reduced dose of			
the product			_
Give best estimate of duration			_
Is therapy still on-going?		ondition was it supposed to treat) 1 of	2710
Returned to Manufacturer On			
ction D - About the Medical De	ovico		_
Name of medical device	evice		_
Name of the company that makes the medical device			_
Model Number	1		_
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			_
Was someone operating the medical device when the problem occurred?			
or implanted medical devices C	NLY (such as pacemak	ers, breast implants, etc.)	
ate the implant was put in		Date the implant was taken out (If relevant)	
ction E - About the Person Wh			
And A location into a distance of the location of the second system of the second system of the second system of the	(b)(6)		-
Sex	Male		
Gender	Cisgender man/boy		_
Please Specify Other Gender			
Age (specify unit of time for age)	2 Year(s)		
Date of Birth			_
Weight	11.7 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska N Native Hawalian or Other Pa		

PECEIDEND: PSG1-1179000	Receipt No: RCT-11	79805			
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CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
Please list all allergies (such as to drugs, foods, pollen or others)	100
NKA	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
None	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies be	ing used.
None	

Section F - About the Perse	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	$(l_{\rm L})(c)$	
Number/Street	=(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	$(l_{r})(c)$	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1179805 FDA 35008 Form CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag es: 5

Fax		Г
Reporter Organization		Γ
Department		Γ
Reporter Speciality		Γ
Today's date	14-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Basic Details	5		12	
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	15-Nov-2023	CTU Received Date	15-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Direct			

ntact se First Name	Last Name	Email Address	Phone		
porter			Flidite		
(b)(6)	(b)(6)	(b)(6)	(b)(6)		
tion A - About the Problem					
What kind of problem was it? (Check all that apply)	Used a product incorrectly Noticed a problem with the	e effect (including new or worsening sympt which could have or led to a problem quality of the product ng from one product maker to another mak			
Date the problem occurred	25-Oct-2023				
Serious	Yes				
Did any of the following happen? (Check all that apply)	Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Ute-threatening Death Other serious/important me	ermanent harm			
ell us what happened and how additional documents if nece	w it happened (Include ssary)	as many details as possible F	FDA may reach out to you f		
My son who is now 3 as of (b)(6)	lab results came bac	k with high level of lead in his bloc	bd		

levant Test/Laboratory Data			1 of 1	
Test Name	LEAD BLOOD, CAPILLAR Y	Test Date	31-Oct-2023	
Test Result	12.8	Test Unit	MICROGRAMS PER DEC	
Low Test Range	3.5	High Test Range	5.0	

Receipt No: RCT-1175983 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	B	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)		
Section A	- About the Problem			10
	ind of problem was it? all that apply)	Used a product incorrectly v	effect (including new or worsening symptor which could have or led to a problem quality of the product ig from one product maker to another maker	
Date th	e problem occurred	16-Jun-2023		
Serious	1	No		
	Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Birth defect Death Other serious/important medical incident(Please Describe Below)			
	what happened and how onal documents if nece		as many details as possible Fl	DA may reach out to you for
			ne out today as being recalled for le Id not figure out the cause. My loca	

his blood levels tested elevated for lead. For months we could not figure out the cause. My local county health department came and inspected my home and did not find anything. I did give them a sample of this fruit pouch and they said they could not test it. I believe the lead is present in other flavors, please test them. Once my son stopped eating them, his levels went from 8.6 to 1.9. I am hoping it does not cause long term damage for him.

evant Test/Laboratory Data		25.	1 of 2
Test Name	LEAD, BLOOD	Test Date	16-Jun-2023
Test Result	8.6	Test Unit	MICROGRAMS PER MIL
Low Test Range		High Test Range	
More Information Available?		0.	

Receipt No: RCT-1175983

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 5

Relevant Test/Laboratory Data	1		2 of 2
Test Name	LEAD, BLOOD	Test Date	28-Sep-2023
Test Result	1.9	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	
More Information Available?			
Additional Comments			
This was after we stopped givin	ng him the Wana Bana fru	it pouches	
Section B - Product Availability	/		
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the product? (check yes if you are including a picture)	No		
Section C - About the Products	\$	-	1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana fruit pouc	hes	
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	Over-the-Counter	rmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			2
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using t product again?	Doesn't Apply		
Drug Therapy	3		1 of 1
Expiration date	2		2
Lot number	-		
Dosage Form			
Quantity		If Other	

Receipt No: RCT-1175983

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 5

a second s		If Other			
How was it taken or used		If Other	1		
Date the person first started taking or using the product	01-Aug-2022				
Date the person stopped taking or using the product	01-Aug-2023				
Date the person reduced dose of the product					
Give best estimate of duration					
Is therapy still on-going?					
Why was the person using the pr	oduct? (such as	what condition was it suppo	osed to treat)) 10	of 1
Returned to Manufacturer On					
ection D - About the Medical De	evice				
Name of medical device					
Name of the company that					
Name of the company that makes the medical device	e model, cataloo,	lot. serial. or UDI number.	and the expi	iration date. if you o	an
Name of the company that	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The	e model, catalog,	lot, serial, or UDI number, a	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The cate them)	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The cate them) Model Number	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	can
Name of the company that makes the medical device ther identifying information (The cate them) Model Number Catalog Number	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The cate them) Model Number Catalog Number Lot Number	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The cate them) Model Number Catalog Number Lot Number Serial Number	e model, catalog,	lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device ther identifying information (The cate them) Model Number Catalog Number Lot Number Serial Number UDDI Number		lot, serial, or UDI number,	and the expi	iration date, if you o	an
Name of the company that makes the medical device Ther identifying information (The cate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem				iration date, if you o	can

E	ection E - About the Person Who Had the Problem		
Γ	Person's Initials	(b)(6)	
Γ	Sex	Male	
	Gender	Cisgender man/boy	
Γ	Please Specify Other Gender		
Γ	Age (specify unit of time for age)	2 Year(s)	
	Date of Birth		

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Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawailan or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title	a constantes	
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City	1	
State/Province		

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Country	UNITED STATES	
ZIP or Postal code		Ī
Telephone number		ſ
Email address		ľ
Fax		ſ
Reporter Organization		Ī
Department		ľ
Reporter Speciality		ſ
Today's date	30-Oct-2023	Ī
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Receipt No: RCT-1176109 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 6

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	B	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact				
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

ection A - About the Problem	
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	30-Oct-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
Tell us what happened and how ny additional documents if nece	v it happened (Include as many details as possible FDA may reach out to you for ssary)
My son ingested lead contaminate	d apple sauce.

elevant Test/Laboratory Data		11	1 of 1	
Test Name	PEDS LEAD	Test Date	30-Oct-2023	
Test Result	6.7	Test Unit	MICROGRAMS PER DEC	

Receipt No: RCT-1176109

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 6

Low Test Range	0	High Test Range	3.5	
More Information Available?				
ditional Comments				
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ction C - About the Products			1 c	of 1
Suspect	Yes		100	
Primary?	Yes			
Туре	Drug/Biologic			_
This report is about	Food/Medical food			
Name of the product as it	Wana bana			
appears on the box, bottle, or package (Include as many names as you see)				
Name of the company that makes (or compounds) the product	Wana bana			
Product Type(check all that apply)	Compounded by a P Generic Biosimilar	harmacy or an Outsourcing Facility		
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ig Therapy			1 c	of 1
Expiration date	17-Mar-2024			
Lot number	01023:17			
Dosage Form				
Quantity		If Other		
Frequency	Daily	If Other		
How was it taken or used	Oral	If Other		
	01-Jul-2023			

Receipt No: RCT-1176109 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 6

Date the person stopped taking or using the product	25-Oct-2023
Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	
Why was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
Returned to Manufacturer On Section D - About the Medical De	vice
	vice
ection D - About the Medical De	vice
Section D - About the Medical Do Name of medical device Name of the company that makes the medical device	vice model, catalog, lot, serial, or UDI number, and the expiration date, if you can

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

Date the implant was put in	Date the implant was taken out (If relevant)	
Section E - About the Person Who Had the Problem	1	-

Person's Initials	(6)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for age)		-
Date of Birth	(b)(6)	
Weight	10.8 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

			-			-
Recei	int.	No	RCT	-11	761	09
11000	5	110.	1.001			00

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 6

es: 0				
	Asian White Black or Afric	an American		
List known medical cond	itions (Such as diabet	tes, high blood pressu	re, cancer, heart diseas	e, or others)
Please list all allergies (s	uch as to drugs, food	s, pollen or others)		5
List any other important i	information about the	person (such as smok	ing, pregnancy, alcohol	use, etc.)
List all current prescription	on medications and m	edical devices being u	sed.	
Cefdinir				
List all over-the-counter	medications and any v	vitamins, minerals, sup	oplements, and herbal re	emedies being used.
Section F - About the Pe	rson Filling Out This P	Form		1 of 1

ection F - About the Pers	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1176109

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 6

Fax		
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	30-Oct-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	





REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.DSR.M.V1
Report Category	Mandatory Dietary Supplements Report
Submitted	2023-11-01 19:24:16 EST
FDA ICSR ID	2147728
Submitted by	francisco@wanabanafruits.com

Report Identifying Information

Please enter a title to help you identify this report. Consider using your firm's internal case tracking number for simplified recordkeeping	Wanabana Apple cinnamon pouch 2.5 oz
What type of report are you submitting?	Serious adverse event and Product Problem (e.g., defects that may have caused or contributed to a serious adverse event)
Enter the date you received the initial report:	10/27/2023
How did the initial reporter learn of the serious adverse event or product problem? (check all that apply)	Other
If other, please describe	Contacted by the FDA by telephone
Regulatory Status	Mandatory

Contact Information - Manufacturer, Packer, or Distributor Site Information

My account address is the same as the manufacturer, packer, or distributor address	Yes
Organization name	Austrofood S.A.S.
Organization type	Manufacturer
Food facility registration number	14992177026
Country	ECUADOR
Street address line 1	Ave. General Enriquez
Street address line 2	Lote 8 y Tanicuchi
City/Town	Sangolqui
State	 blank>
State/Province	Pichincha
Mail/ZIP Code	 blank>
Postal Code	170501
I am the point of contact for the facility listed above	Yes
First name	Francisco
Last name	Pena
Job title	CEO
Email	francisco@wanabanafruits.com
Confirm email	francisco@wanabanafruits.com
Primary phone	593991036405
Other phone	14073776796
Fax	<blank></blank>

Contact Information- Report Submitter

Contact Information - Initial Reporter

Did the initial reporter indicate that they also reported the event to the FDA? Unknown Does the initial reporter wish to remain anonymous to the FDA? No

Salutation	<blank></blank>
First name	<blank></blank>
Last name	<blank></blank>
Email	<blank></blank>
Confirm email	<blank></blank>
Phone	<blank></blank>
Country	<blank></blank>
Street address line 1	<blank></blank>
Street address line 2	<blank></blank>
City/Town	<blank></blank>
State	<blank></blank>
Mail/ZIP code	<blank></blank>
Was the initial reporter a healthcare professional?	Unknown

Relevant Details

Patient identifier	(b)(6)
Gender	<black></black>
Age at time of event, <i>if unknown, please enter Date of birth below</i>	<blank></blank>
Select unit of measure	<blank></blank>
Date of birth	<black></black>
Weight	<blank></blank>
Select unit of measure	<blank></blank>
Height	<black></black>
Select unit of measure	 slank>

Problem Details

Outcomes attributed to adverse event (check all that apply)	Other serious (important medical events)
If other, please describe	Test result showed elevated concentrations of lead
Date of death	<blank></blank>
Please describe the event or problem	Test result showed elevated concentrations of lead.
Date of event	10/27/2023
Duration of adverse event	1

Select unit of measure	day
Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :	<blank></blank>
Do you have any relevant tests/laboratory data information to report?	No

Adverse Event Terms

Relevant Tests/Laboratory Data

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Wanabana Apple cinnamon fruit puree 2.5 oz x 3 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	2.5
Select unit of measure	CZ.
Barcode identifier	7862118149278
Select identifier type	Other
If other, please describe	Pack X3 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	11022:11
Expiration/use-by date	01/10/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	12/09/2022
End:	10/28/2023
Duration of product use	14

month(s)
1
day(s)
2.5
az
oral
Not Applicable
Not Applicable
<blank></blank>

Ingredient name	Apple puree
If other, please describe	Apple puree
Ingredient amount	70.87
Select unit of measure	9

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.09
Select unit of measure	9

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.04
Select unit of measure	9

Product Information

Other
Schnucks cinnamon applesauce 3.2oz X 4 units
Austrofood S.A.S.
3.2
02
041318011555
Other
Pack x4 units
Product ready to eat
05023:19
07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz.
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank></blank>
Did the event reoccur when product use resumed?	<blank></blank>
Please provide any notes describing the product's usage.	<blank></blank>

Ingredient Details

Ingredient name Apple

If other, please describe Apple

Ingredient amount 70.60

Select unit of measure g

Ingredient Details

Ingredient name Apple puree concentrate If other, please describe Apple puree concentrate Ingredient amount 18.90 Select unit of measure g

Ingredient Details

Ingredient name Cinnamon powder If other, please describe Cinnamon powder Ingredient amount 0.45 Select unit of measure g

Ingredient Details

Ingredient name CITRIC ACID

Ingredient amount 0.05

Select unit of measure g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Weis cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	az
Barcode identifier	041497216123
Select identifier type	Other
If other, please describe	Pack x 20 units

Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:28
Expiration/use-by date	07/28/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	az
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank></blank>
Did the event reoccur when product use resumed?	<blank></blank>
Please provide any notes describing the product's usage.	<blank></blank>

Ingredient Details

Ingredient name	Apple	
If other, please describe	Apple	
Ingredient amount	70.60	
Select unit of measure	9	

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Ingredient name	Cinnamon powder	
If other, please describe	Cinnamon powder	
Ingredient amount	0.45	
Select unit of measure	9	

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	9

Product Information

.

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz X 12 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz.
Barcode identifier	041318011524
Select identifier type	Other
If other, please describe	Pack x 12 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please

stimate duration of use below. Start:

End: 10/28/2023

Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank></blank>
Did the event reoccur when product use resumed?	<blank></blank>
Please provide any notes describing the product's usage.	<blank></blank>

Ingredient name	Apple	
If other, please describe	Apple	
Ingredient amount	70.60	
Select unit of measure	9	

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	9

Ingredient Details

Ingredient name	Cinnamon powder	
If other, please describe	Cinnamon powder	
Ingredient amount	0.45	
Select unit of measure	9	

Ingredient name CITRIC ACID

Ingredient amount 0.05

Select unit of measure g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz X 20 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	cz.
Barcode identifier	041318011579
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Producto ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	az
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank></blank>

<blank></blank>	Did the event reoccur when product use resumed?
	Please provide any notes describing the

ease provide any notes describing the product's usage.

Ingredient Details

Ingredient name	Apple	
If other, please describe	Apple	
Ingredient amount	70.60	
Select unit of measure	9	

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	9

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	9

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	9

Product Relevant Details

I have reviewed the ingredients listed for

each product, if available, and made any Yes necessary corrections

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Apple Cinnamon Fruit Puree 2.5oz x 3 unit
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	2.5
Select unit of measure	az
Barcode identifier	782118149278
Select identifier type	Other
If other, please describe	Pack x 3 units
Diagnosis or reason for use (indication):	 slank>
Lot number	11022:10
Expiration/use-by date	01/10/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	12/09/2022
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	week(s)
Amount consumed per serving	2.5
Select unit of measure	oz.
Administration route	oral
Please provide any notes describing the product's usage:	<blank></blank>

Concomitant Ingredient Details

If other, please describe Apple puree

Ingredient amount 70.87

Select unit of measure g

Concomitant Ingredient Details

Ingredient name Cinnamon powder

If other, please describe Cinnamon powder

Ingredient amount 0.09

Select unit of measure g

Concomitant Ingredient Details

Ingredient name CITRIC ACID

Ingredient amount 0.04

Select unit of measure g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz x 4 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	az
Barcode identifier	041318011555
Select identifier type	Other
If other, please describe	Pack x 4 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Concomitant Product Use Details

<blank></blank>
10/28/2023
14
month(s)
1
day(s)
3.2
az
oral
<blank></blank>

Apple
Apple
70.60
9

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	9

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	9

Ingredient name CITRIC ACID

If other, please describe <blank>

Ingredient amount 0.05

Select unit of measure g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Weis cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	œ
Barcode identifier	041497216123
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:28
Expiration/use-by date	07/28/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	<blank></blank>

Ingredient name Apple If other, please describe Apple Ingredient amount 70.60 Select unit of measure g

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	9

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name CITRIC ACID

Ingredient amount 0.05

Select unit of measure g

Concomitant Product Information

Select full name of product as it appears on the package label

Other

Full name of product as it appears on the Schnucks cinnamon applesauce 3.2oz x 12 units package label

Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	az
Barcode identifier	041318011524
Select identifier type	Other
If other, please describe	Pack x 12 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	0Z.
Administration route	oral
Please provide any notes describing the product's usage:	<blank></blank>

Concomitant Ingredient Details

Ingredient name	Apple	
If other, please describe	Apple	
Ingredient amount	70.60	
Select unit of measure	9	

Concomitant Ingredient Details

Ingredient name Apple puree concentrate

If other, please describe Apple puree concentrate Ingredient amount 18.90

Select unit of measure g

Concomitant Ingredient Details

Ingredient name Cinnamon powder If other, please describe Cinnamon powder

Ingredient amount 0.45

Select unit of measure g

Concomitant Ingredient Details

Ingredient name CITRIC ACID

Ingredient amount 0.05

Select unit of measure g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	œ
Barcode identifier	041318011579
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024
Product strength Select unit of measure Barcode identifier Select identifier type If other, please describe Diagnosis or reason for use (indication): Lot number	oz 041318011579 Other Pack x 20 units Product ready to eat 05023:19

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank></blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	Prodcut ready to eat

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	9

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	9

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	9

Ingredient name CITRIC ACID

Ingredient amount 0.05

Select unit of measure g

Concomitant Product Relevant Details

I have reviewed the ingredients listed for each product, if available, and made any Yes necessary corrections

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id SRPCIT

HL7 Batch Sender Information

Sender Id	SRPCIT
Job Title	Mandatory Dietary Supplement Submitter
Phone	593991036405
Email	francisco@wanabanafruits.com

HL7 Batch Receiver Information

Batch Receiver (Root) USFDA

Batch Receiver (Extension) US Food and Drug Administration

HL7 Message Information

HL7 Message Control Information

Unique Sender Identifier SRPCIT

Profile Identifier FPSR.FDA.DSR.M.V1.ACCOUNT.AEPP

HL7 Message Sender Information

Unique Sender Identifier ID-14992177026

Organization Name Austrofood S.A.S.

Title Mandatory Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

None

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	02-Nov-2023	CTU Received Date	02-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	B	
User/Group			
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	28-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
ell us what happened and how additional documents if nece	w it happened (Include as many details as possible FDA may reach out to you fo issary)

Relevant Test/Laboratory Data 1 of 1 BLOOD TEST (CAPILLAR Test Date Test Name 01-Nov-2023 Y) Test Result 28.8 Test Unit MICROGRAMS PER DEC ILITRE Low Test Range 0 High Test Range 3.4

getting a venous blood test tomorrow to confirm the level.

Receipt No: RCT-1177213

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag es: 5

More Information Available?				
dditional Comments				
ection B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
ection C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical foor	d		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Apple	e Cinnamon		
Name of the company that makes (or compounds) the product				
Product Type(check all that apply)	Over-the-Counter	a Pharmacy or an Outsourcing Fa	cilty	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ug Therapy		-		1 of 1
Expiration date				
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other	1	
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				

Receipt No: RCT-1177213 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag.

08:5

Date the person reduced dose of the product	
Give best estimate of duration	6 Month
Is therapy still on-going?	Yes
/hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1
Returned to Manufacturer On	
Tretuined to manufacturer off	
ection D - About the Medical De	wice
Name of medical device	
Name of the company that	
makes the medical device	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
cate them)	model, catalog, lot, senal, or obtinumber, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the	
medical device when the problem	
occurred?	
or implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)
ate the implant was put in	Date the implant was taken out (If relevant)
	Televally
ection E - About the Person Wh	o Had the Problem
Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	1 Year(s)
Date of Birth	
Weight	10.35 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	
concrete there are a set to the the to	American Indian or Alaska Native

Recei	int	No:	RCI	F-11	77213

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag es: 5

White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Please list all allergies (such as to drugs, foods, pollen or others)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
	_
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Receipt No: RCT-1177213 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag es: 5

Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	02-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Receipt No: RCT-1177498 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 6

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details						
Company Unit	CDER-CTU	Originating Account	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority	Routine					
Override Auto Calculation Rule	No					
FDA Received Date	03-Nov-2023	CTU Received Date	04-Nov-2023			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User	B				
User/Group						
Forward to Department	CDER (CDER-C	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct					

Contact	- Mi	155	100	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Г	Date the problem occurred	30-Oct-2023	
Г	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Ulfe-threatening Death Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

The wanabana brand fruit purée pouches were recalled so I had my daughters blood lead level tested and it came back 15.5 mcg/dl, she began becoming extremely fussy, irritable, sleeping less and loss of appetite.

elevant Test/Laboratory	Data		1 of 1
Test Name	LEAD (VENOUS)	Test Date	30-Oct-2023
Test Result	15.5	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 6

More Information Available?				
ditional Comments				
ction B - Product Availability		-		
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ction C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food	Ì		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Apple cinnamon fr	uit puree		
Name of the company that makes (or compounds) the product	Wanabana			
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Fac	ity	
Strength		If Other		
NDC number		L analogica		
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
ig Therapy				1 of 1
Expiration date	31-Mar-2024			
Lot number	01023311205			
Dosage Form		9		
Quantity		If Other		
Frequency		If Other		
How was it taken or used	Oral	If Other		
Date the person first started taking or using the product	20-Sep-2023			
Date the person stopped taking or using the product	30-Oct-2023			

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 6

Date the person reduced dose of the product	30-Oct-2023			
Give best estimate of duration				
Is therapy still on-going?				
hy was the person using the p	oduct? (such	as what co	ondition was it supposed to trea	t) 1 of 1
To eat				
Returned to Manufacturer On				
ection D - About the Medical D	wice			
Name of medical device	SVIGG			
Name of the company that makes the medical device				
ther identifying information (The cate them)	e model, cata	ilog, lot, ser	ial, or UDI number, and the exp	iration date, if you can
Model Number				
Catalog Number				
Lot Number				
Serial Number				
UDDI Number			S	
Expiration date				
Was someone operating the medical device when the problem occurred?				
or implanted medical devices C	NLY (such a	s pacemak	ers, breast implants, etc.)	
Date the implant was put in			Date the implant was taken out (It relevant)	f
				-
ection E - About the Person Wi		robiem		
Person's Initials	(b)(6)			
Sex	Female			
Gender	Cisgender wo	oman/girl		
Please Specify Other Gender				
Age (specify unit of time for age)	(b)(6)	_		
Date of Birth	(b)(6)			
Weight	10.35 kg			
Ethnicity (Choose only one)	Not Hispanic	Latino		
Race (Check all that apply)		dian or Alaska N silan or Other Pa		

Recei	int.	No	RC	C-14	77498
Rece	ຍເ	INO:	150		111490

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 6

White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Please list all allergies (such as to drugs, foods, pollen or others)	
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medications and medical devices being used.	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

1

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 6

Fax		
Reporter Organization		Γ
Department		Г
Reporter Speciality		Г
Today's date	03-Nov-2023	Г
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	Γ
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



Receipt No: RCT-1177403 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2	14 (A)	13		
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine	Routine			
Override Auto Calculation Rule	No				
FDA Received Date	03-Nov-2023	CTU Received Date	03-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User	User			
User/Group					
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct				

ase First Name	Last Name	Email Address	Phone
(b)(6)	(b)(6)	(b)(6)	
ction A - About the Pro	oblem		
What kind of problem wa (Check all that apply)	Used a product incorrectly Noticed a problem with th	ide effect (including new or worsening sympto y which could have or led to a problem e quality of the product hing from one product maker to another make	
Date the problem occurr	ed 31-Oct-2023		
Serious	No		
Did any of the following (Check all that apply)		permanent harm m nedical incident(Please Describe Below)	
ell us what happened additional document		e as many details as possible F	DA may reach out to you fo
We were made aware of these pouches so we ca	a recall for Wanabana fruit pouch led our pediatric office and they re	es as they contained high levels of l commended that our daughter get a had high levels of lead, though not h	a blood draw to check her lead

immediate medical attention. We were advised to check her blood again in 6 months.

elevant Test/Laboratory Data		NY	1 of 1
Test Name	BLOOD TEST FOR LEAD	Test Date	31-Oct-2023
Test Result	5	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.5
More Information Available?		6.	

Generated by: SYSTEM

Additional Comments Section B - Product Availability Do you still have the product in No case we need to evaluate it? Do you have a picture of the No product? (check yes if you are including a picture) 1 of 1 Section C - About the Products Suspect Yes Primary? Yes Type Drug/Biologic This report is about Name of the product as it Wana Bana Apple Cinnamon Fruit Puree appears on the box, bottle, or package (Include as many names as you see) Name of the company that Wana Bana makes (or compounds) the product Product Type(check all that Over-the-Counter apply) Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar If Other Strength NDC number Did the problem stop after the No person reduced the dose or stopped taking or using the product? Did the problem return if the Doesn't Apply person started taking or using the product again? Drug Therapy 1 of 1 Expiration date Lot number Dosage Form If Other Quantity As needed If Other Frequency How was it taken or used If Other Oral Date the person first started 01-Jul-2022 taking or using the product Date the person stopped taking 01-Nov-2023 or using the product Date the person reduced dose of the product

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 5

Give best estimate of duration			
Is therapy still on-going?			
Why was the person using the pr	oduct? (such as what cond	fition was it supposed to treat)	1 of 1
Food			
Returned to Manufacturer On			
Section D - About the Medical De	vice		
Name of medical device			2
Name of the company that makes the medical device Other identifying information (The ocate them)	model, catalog, lot, serial,	, or UDI number, and the expirat	ion date, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
or implanted medical devices O	NLY (such as pacemakers	, breast implants, etc.)	
Date the implant was put in	1	Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem		
Person's Initials	(b)(6)		
Sex	Female		
Gender	Cisgender woman/girl		1
Please Specify Other Gender			
Age (specify unit of time for age)			
Date of Birth	(b)(6)		
Weight	9 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Nativo		

THE STATE WITH THE REAL PROPERTY OF THE STATE OF THE STAT
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
N/A
Please list all allergies (such as to drugs, foods, pollen or others)
N/A
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
N/A
List all current prescription medications and medical devices being used.
None
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
Vitamin D

Section F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(6)(6)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number	-	
Email address	(b)(6)	
Fax		
Reporter Organization		

Receipt No: RCT-1177403 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 5

Department		
Reporter Speciality		
Today's date	03-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1177845 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81881 | Department: CFSAN | RCT No.: RCT-1177845 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	B	
User/Group			
Forward to Department			
Case Priority	Direct		

ontact				
aso	First Name	Last Name	Email Address	Phone
eporter	(b)(6)	(b)(6)	(b)(6)	(b)(6)
ction A -	About the Problem			
	nd of problem was it? all that apply)	Used a product incorrec Noticed a problem with	side effect (including new or worsening sy thy which could have or led to a problem the quality of the product ching from one product maker to another r	
Date the	problem occurred	06-Jun-2023		
Serious		Yes		
Did any of the following happen?				
	Prious/important medical Please Describe Below)			
	hat happened and how nal documents if nece		le as many details as possibl	e FDA may reach out to you fo
house, h pouches	is daycare, and family me	embers houses tested in	after having a baseline of no lead including the soil and water with no how he obtained lead posioning.	d 6 months prior. We had our b answer. He eats "wanna banana" 1 of 1
Test Nar		LEAD	Test Date	06-Jun-2023
Test Res		11	Test Unit	

Low Test Range

0

High Test Range

Receipt No: RCT-1175836 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag es: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			44
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Case	First Name	Last Name	Email Address	Phone	
Reporter					
Z	(b)(6)	(b)(6)	(b)(6)	(b)(6)	
ection A	- About the Problem				
and the second sec	ind of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the o	effect (including new or worsening sympto hich could have or led to a problem uality of the product g from one product maker to another maker		
Date the problem occurred Serious		22-Aug-2023			
		Yes			
Did any of the following happen? (Check all that apply)		Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important met			
	erious/important medical t(Please Describe Below)				

My son ate Apple Cinnamon WanaBana fruit puree pouches as a regular in through August 2023. He had his blood lead levels tested on 8/22/2023 as came back as 19.8ug/dL. The pediatrician, (b)(6) source of exposure, but home studies, dust wipes, and the XRF gun did nu home. Additionally, my husband and I hired an independent company to p lead exposure in the home. Daycare was also deemed to be an unlikely so my son's licensed daycare had elevated lead levels on their tests. Since m lead poisoning healthy diet, and in doing so, have eliminated the WanaBa diet. His blood lead levels test was repeated on 9/1/2023, 9/14/2023, 9/26 22.4ug/dL, 14.3ug/dL, and 9.6ug/dL respectively. My son is currently in the lead poisoning and is enrolled in the local (b)(6) His levels are trending down, but we are extremely concerned about future resulting from this exposure.	s part of a routine screening for daycare and they Health department were working to identify the lot detect a source of exposure for my son in our berform a separate study that yielded no source of ource of exposure as none of the other children at my son's diagnosis, we have been following the EPA's ina apple cinnamon fruit puree pouches from his 3/2023, and 10/25/2023. The results were 22.5ug/dL, eatment at (b)(6) for as a result of this lead exposure.

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag es: 7

evant Test/Laboratory I	Data		1 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	22-Aug-2023
Test Result	19.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	?		
evant Test/Laboratory I	Data	W.	2 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	01-Sep-2023
Test Result	22.5	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	9?		
evant Test/Laboratory (Data		3 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	14-Sep-2023
Test Result	22.4	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	9?		
evant Test/Laboratory (Data		4 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	26-Sep-2023
Test Result	14.3	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	9?		
evant Test/Laboratory (Data	6	5 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	25-Oct-2023
Test Result	9.6	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available	2		

Additional Comments

Section B - Product Availability

Do you still have the product in Yes case we need to evaluate it?

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag es: 7

Do you have a picture of the product? (check yes if you are including a picture)	Yes				
Section C - About the Products			1 of 1		
Suspect	Yes			Γ	
Primary?	Yes		t		
Туре	Drug/Biologic	rug/Biologic			
This report is about	Food/Medical food	ood/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple	WanaBana Apple Cinnamon Fuit Puree "I Am Fruit"			
Name of the company that makes (or compounds) the product	WanaBana LLC, AUSTROFOOD				
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Facility			
Strength		If Other		1	
NDC number				\square	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Dr				
Did the problem return if the person started taking or using the product again?	Doesn't Apply				
Drug Therapy			1 of 1		
Expiration date	31-Dec-2023				
Lot number	10022:31 08:10				
Dosage Form		8 m	any .		
Quantity	Other	If Other	2.5 Ounce(s)		
Frequency	Other	If Other	4-6 pouches/day		
How was it taken or used	Oral	If Other			
Date the person first started taking or using the product	01-May-2023	Marin			
Date the person stopped taking or using the product	31-Aug-2023				
Date the person reduced dose of the product					
Give best estimate of duration				-	
Is therapy still on-going?					
Why was the person using the pr It was marketed as food for babie			osed to treat) 1 of 1		
Returned to Manufacturer On				Ē	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag es: 7

Section D - About the Medical D	evice
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (Th locate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
ANT SALDING THE REAL MOVE	
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices C	NLY (such as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If relevant)
Section E - About the Person Wi	no Had the Problem
Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	11.61 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	
The control of the company	American Indian or Alaska Native
	Native Hawaiian or Other Pacific Islander
	Asian W White
	Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Elevated Blood Lead Level

Please list all allergies (such as to drugs, foods, pollen or others)

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag es: 7

N/a

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

N/A

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. Poly-Vi-Sol

ction F - About the Person Fil	ling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City	(-)(-)	
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number	(0)(0)	
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	30-Oct-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your identity disclosed to the	No	



FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Case Priority Direct			

Contact	Contact				
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Г	Date the problem occurred	09-Oct-2023	
Г	Serious	No	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident/Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My child was one year old 10/7/23 and had for several weeks started to eat applesauce Loved this particular brand. Would eat 2-3 a day. On 10/9/23 we had his one year check up and found out he was severely anemic. The loose stools (initially thought was caused by breast milk) turned into explosive diarrhea that smelled like death He was having these stools 3-4 times a day Then I saw This recall Our pcp wants to wait 3-4 weeks to do a blood test. But we will definitely be doing one.

Relevant Test/Laboratory	Data	6.	1 of 1
Test Name	IRON	Test Date	09-Oct-2023
Test Result	Low (don't remember exac t number)	Test Unit	
Low Test Range		High Test Range	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 7

More Information Available?				
dditional Comments				
PCP is (b)(6)				
Section B - Product Availability				70
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the product? (check yes if you are including a picture)	Yes			
ection C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food	E .		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple	puree pouches		
Name of the company that makes (or compounds) the product	WanaBana apple	puree pouches		
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Faci	Bty	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
rug Therapy				1 of 1
Expiration date	21-Sep-2024			
Lot number	07023211542			
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Aug-2023			
Date the person stopped taking or using the product	30-Oct-2023			

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 7

Date the person reduced dose of			
the product Give best estimate of duration			
Is therapy still on-going? Why was the person using the pr	aduat2 (auch ac what acad		1 of 1
why was the person using the p			
Returned to Manufacturer On			
Section D - About the Medical De	wice		
Name of medical device	WICE		
Name of the company that			
makes the medical device Other identifying information (The	model catalon lot social	or LIDL number, and the evolved	ion date, if you can
ocate them)	ritiouel, catalog, iot, serial,	or opi number, and the expirat	ion date, ir you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
For implanted medical devices O	NLY (such as pacemakers	, breast implants, etc.)	
Date the implant was put in	C	Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem		
Person's Initials	0.00		~
Sex	Male		
Gender	Not selected		
Please Specify Other Gender			
Age (specify unit of time for age)	1 Year(s)		
Date of Birth			
Weight	12.6 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Native		

FDA 3500B Form

CTU No.: FDA-CDER-CTU es: 7	U-2023-80170 Department: CFSAN RCT No.: RCT-1176178 CTU Triage Date: 31-Oct-2023 Total Pag
	White Black or African American
	onditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
None	
The second s	s (such as to drugs, foods, pollen or others)
None	
and provide the second s	nt information about the person (such as smoking, pregnancy, alcohol use, etc.)
None	
and the second se	ption medications and medical devices being used.
None	
ist all over-the-count	er medications and any vitamins, minerals, supplements, and herbal remedies being used.
None	

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	$(\mathbf{b})(\mathbf{c})$	
Number/Street	=(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	$(\mathbf{b})(\mathbf{c})$	
Telephone number	(b)(6)	
Email address		

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag es: 7

Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	30-Oct-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No





ocksonville FL 32209. e-272-7184 0052-8PM-AN-0818 Imp 203

dry place. Once perate and sin 5 days.

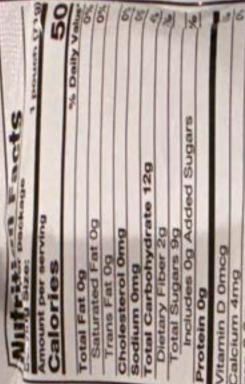
Mis package has a mis product's cap

ackagino

products visit:



00



Calcium 4mg

Iron 0.2mg

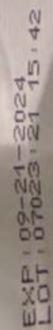
6 δ

Potassium 60mg

serving of food contributes to a daily diet. 2,000 calories a day - The % Daily Value (DV) tells you how much a nut used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder acidulant: citric acid.

Batch N° / Produced / Best by / see package NOT SUITABLE FOR MICROWAVE





FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag es: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	01-Nov-2023	CTU Received Date	01-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Priority	Direct				

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
ection A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the o	effect (including new or worsening sympto hich could have or led to a problem pality of the product g from one product maker to another maker	
Date the	e problem occurred	20-Jun-2023		
Serious		No		
(Check	of the following happen? all that apply)			DA may reach out to you fo
	onal documents if neces		is many details as possible r	DA may reach out to you to
finger p more ac and we raised of later tha health o of her fo pouche	rick that came back as a 14 ccurate number that will be had the (b)(6) Hea concerns for lead. After that at came back higher than th lepartment to come back o bod. After a month of trying	I lead count, after they four shown below in relevant to the Department come out to meeting with the health de e first blood draw, so she ut to do another check, the to get the health department	appointment on 6/1/2023 and had nd those numbers we were asked asts. The blood drawn test came b to do a check and they couldn't fin apartment they asked us to do and was still being exposed with no an ay didn't think it was necessary to do and to come back out, the FDA rele daughter had been consuming the	to get a blood draw to get a ack with still raised lead levels d anything that they didn't think other blood draw 3 months swers. After trying to get the check our homes, toys, or any based that the Wanabana Purée

levant Test/Laborato	ry Data	57	1 of 2
Test Name	LEAD BLOOD TEST	Test Date	20-Jun-2023
Test Result	7.1 mcg/dL	Test Unit	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag es: 7

Low Test Range	< 3.5	High Test Range		
More Information Available?		W		
levant Test/Laboratory Data		<u>8</u>	2 of 2	2
Test Name	LEAD BLOOD TEST	Test Date	11-Sep-2023	
Test Result	8.5 mcg/dL	Test Unit		
Low Test Range	< 3.5	High Test Range		
More Information Available?				
ditional Comments				
				_
ction B - Product Availability				
Do you still have the product in case we need to evaluate it?	Yes			
Do you have a picture of the	Yes			
product? (check yes if you are including a picture)	100.0			
ction C - About the Products	1		1 of	1
Suspect	Yes		T OI	-
Primary?	Yes			_
per a construction a series and ser				_
Type This second is about	Drug/Biologic			_
This report is about	Food/Medical food			_
Name of the product as it appears on the box, bottle,	Wanabana purée pouch			
or package (Include as many				
names as you see)				
Name of the company that makes (or compounds) the				
product				
product	-			
Product Type(check all that	Over-the-Counter			
		cy or an Outsourcing Facility		
Product Type(check all that		cy or an Outsourcing Facility		
Product Type(check all that apply)	Compounded by a Pharma			
Product Type(check all that apply) Strength	Compounded by a Pharma	cy or an Outsourcing Facility		
Product Type(check all that apply)	Compounded by a Pharma			
Product Type(check all that apply) Strength NDC number Did the problem stop after the	Compounded by a Pharma			
Product Type(check all that apply) Strength NDC number Did the problem stop after the person reduced the dose or	Compounded by a Pharma			
Product Type(check all that apply) Strength NDC number Did the problem stop after the	Compounded by a Pharma			
Product Type(check all that apply) Strength NDC number Did the problem stop after the person reduced the dose or stopped taking or using the product? Did the problem return if the	Compounded by a Pharma Generic Biosimitar			
Product Type(check all that apply) Strength NDC number Did the problem stop after the person reduced the dose or stopped taking or using the product? Did the problem return if the person started taking or using the	Compounded by a Pharma Generic Biosimitar			
Product Type(check all that apply) Strength NDC number Did the problem stop after the person reduced the dose or stopped taking or using the product? Did the problem return if the person started taking or using the product again?	Compounded by a Pharma Generic Biosimitar		 1 of	1
Product Type(check all that apply) Strength NDC number Did the problem stop after the person reduced the dose or stopped taking or using the product? Did the problem return if the person started taking or using the	Compounded by a Pharma Generic Biosimitar		1 of	1

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag es: 7

Dosage Form			
Quantity		If Other	
Frequency	Twice a day	If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product		1.16	
Date the person stopped taking or using the product			
Date the person reduced dose of the product			
Give best estimate of duration	7 Month		
Is therapy still on-going?			
hy was the person using the pr	oduct? (such as w	hat condition was it supposed	to treat) 1 of 1

Returned to Manufacturer On

Section D - About the Medical De	vice
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The ocate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
C. (IN IN	
Serial Number	
UDDI Number	

- 10 C		a		100 L	4.15
Date	the	implant	was	put	in

Date the implant was taken out (If relevant)

1	Section E - About the Person W	/ho Had the Problem	
Г	Person's Initials	(D)(G)	
Γ	Sex	Female	
Γ	Gender	Cisgender woman/girl	
Γ	Please Specify Other Gender		

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag es: 7

Age (specify unit of time for age)		
Date of Birth	(b)(6)	Γ
Weight	11.7 kg	Γ
Ethnicity (Choose only one)	Not Hispanic/Latino	Г
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or others)

N/A

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

N/A

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

N/A

Section F - About the Person Filling Out This Form		1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	(0)(0)	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag es: 7

City	(b)(6)
State/Province	(0)(0)
Country	UNITED STATES
ZIP or Postal code	$(l_{r})(c)$
Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	01-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

CTU No.: FDA-COER-CTU-2023-80914 | Department: CESAN | ROT No : RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag ep: 7



CTU No.: FDA-COER-CTU-2023-80914 | Department: CESAN | ROT No : RCT-1178847 | CTU Triage Date: 02-Nov-2023 | Total Pag ep: 7





FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 4

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	03-Nov-2023	CTU Received Date	03-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

A	PATIENT INFORMATION		
Г	Patient Identifier (In Confidence)	80.01	
Г	Age	17 Month(s)	
Г	Date of Birth		
Г	Sex	Female	
Г	Gender	Decline to answer	
Г	Please Specify Other Gender		
Г	Weight	9 kg	
	Ethnicity (Check single best answer)	Not Hispanic/Latino	
	Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander	

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine	
Serious	Yes	Γ
Outcome Attributed to Adverse Event (Check all that apply)	Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 4

Date of Death	Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage	
Date of Event	01-Nov-2023	
Date of this Report	03-Nov-2023	

Density Frank Distance Distance Distance

Describe Event, Problem, or Product Use Error: was eating WanaBana fruit pouches. family heard of recall and obtained lead level: 11/1 result 10.8; of note prior lead obtained for routine screening 5/16/23 was <1. These were both venous lead levels

		1 of 1
LEAD VENOUS	Test Date	01-Nov-2023
10.8	Test Unit	MICROGRAMS PER DEC
	High Test Range	
	0.000	LEAD VENOUS Test Date 10.8 Test Unit

Other Relevant History, Including Preexisting Medical Conditions

C	2. PRODUCT AVAILABILITY				
Γ	Product Available for Evaluation? (Do not send product to FDA)	No			
Г	Returned to Manufacturer on				
	Do you have a picture of the product? (check yes if you are including a picture)	No			

D. PRODUCT(S)		1 of 1
Suspect	Yes	
Primary?	Yes	
Туре	Drug/Biologic	
This report involves:	Food/Medical food	
Name,Strength,Manufacture	r/Compounder (from product label)	
Product Name	WanaBana fruit pouch	
Strength	If Other	
Manufacturer/Compounder		

es: 4

NDC# or Unique ID			
Product Type(check all that apply)	Compounded Generic Biosimilar		
Event Abated After Use Stopped or Dose Reduced?	Yes		
Event Reappeared after Reintroduction ?	Doesn't Apply		7.923.9
g Therapy			1 of 1
Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?		10	
Lot Number			

E. SUSPECT MEDICAL DEV	ICE	
Brand Name		
Common Device Name		
Procode		
Manufacturer Name		
City		
State		
Model #		
Lot #		
Catalog #		
Expiration Date		
Serial #		
Unique Identifier (UDI)#		
Operator of Device	Health Professional Patient/Consumer Other	
Other		
If Implanted, Give Date		

CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pages: 4

If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER			1 of 1	
Primary?	Yes			Τ
Reporter is Patient?				T
Title				T
Last Name	(b)(6)			Τ
Middle Name				
First Name	(b)(6)			
Address	(b)(6)			T
City	(0)(0)			
State/Province/Region	••••			
Country	UNITED STATES	If Other		
ZIP/Postal Code	(h)(G)		12	
Phone	(b)(6)			
Email	(-)(-)			
Fax				Τ
Reporter Organization				Τ
Department				
Reporter Speciality				
Health Professional?	Yes	877	72	
Occupation	Physician	If Other		
Also Reported to	Manufacturer/Comp			
If you do NOT want your identity disclosed to the manufacturer	Yes			

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	03-Nov-2023	CTU Received Date	04-Nov-2023	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A	- About the Problem			200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200 - 200
	nd of problem was it? all that apply)	Used a product incorrectly v	effect (including new or worsening sympto which could have or led to a problem quality of the product ig from one product maker to another make	
Date the	e problem occurred	24-Oct-2023		
Serious		No		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death Other serious/important med	rmanent harm	
	what happened and how onal documents if nece		as many details as possible F	DA may reach out to you for
his bab an 5am weeken over the When I WanaB	ysitter reported to me that vomiting. I called my sons id for signs of dehydration, weekend. He was seen a returned home I laid my so ana apple cinnamon pouch	he didn't have much of an a pediatrician to make an ap if no improvement by Mon ther pediatricians office M on down for a nap. After do nes. Immediately I called hi	appetite all day. The following mo ppointment. They advised me to w day they would see him in clinic. I londay Oct 30 where he was diago ing so I got online and saw a new is doctor back to report my concer- son to the lab at the hospital to ha	ming 10/26/23 my son woke up vatch my son closely over the He had vomiting and diarrhea nosed with the stomach flu. rs article about an Urget recall for m. I left a message with the front

levels. I had previous doctor orders from my sons 1 year wellness visit. I received his results today and hid lead levels were above range. His pediatrician just recommended retesting in January. My sons symptoms did resolve on Wednesday 11/1/23. No reoccurring symptoms since. I am concerned his flu like symptoms were from the lead exposure in this recalled product.

R€	elevant Test/Laboratory Data	aboratory Data 1 of 1				
	Test Name	LEAD LEVEL BLOODWO RK	Test Date	30-Oct-2023		

FDA 3500B Form

Do you still have the product in case we need to evaluate it? No Do you have a picture of the product? (check yes if you are including a picture) Yes Section C - About the Products 1 of 1 Suspect Yes Type Drug/Biologic This report is about Food/Medical food Name of the product as it appears on the box, bottle, or package (include as many names as you see) WanaBana Cinnamon applesauce pouch applesauce pouch applesauce pouch applesauce pouch applesauce pouch applesauce pouch appears on the box, bottle, or package (include as many names as you see) WanaBana Name of the company that makes (or compounds) the product applesauce pouch a				
More Information Available? Additional Comments Section B - Product Availability Do you stil have the product in case we need to evaluate n? Do you stil have the product in case we need to evaluate n? Yes Priduct? (check yes if you are including a picture) Yes Section C - About the Products Type DrugBiologic This report is about Food/Medical food Name of the product as it appears on the box, bottle, or package (Include as many names as you see) WanaBana Name of the compounds) the product Type(check all that apply) WanaBana Product Type(check all that apply) WanaBana Did the problem stop after the person reduced the dose or stopped taking or using the product again? If Other NDC number Odoes the Counter apply) 1 of 1 Did the problem stop after the person reduced the dose or stopped taking or using the product again? If Other Did the problem stop after the person stop after the person reduct taking or using the product again? 1 of 1 Expiration date 25-Jun-2024 1 of 1 Expiration date 25-Jun-2024 1 of 1 Chantify If Other 1 of 1 Expiration date	Test Result	4.2	Test Unit	GRAMS PER LITRE
Additional Comments Additional Comments Soction B - Product Availability Do you still have the product in case we need to evaluate if? Do you shave a picture of the product? (check yes if you are including a picture) Section C - About the Products I of 1 Suspect Yes Type Drug/Biologic This report is about Food/Medical food Name of the product as it appears on the box, botte, or package (Include as many, names as you see) Name of the compands) the product Type(check all that apply) ManaBana I of other the compands) the product Type(check all that apply) Did the problem stop after the product as it appears on the product in Strength I of the problem stop after the product? Product Type(check all that appears on the stop after the product again? Did the problem	Low Test Range		High Test Range	
Section B - Product Availability Do you still have the product in case we need to evaluate it? No Do you have a picture of the product? (Neek yes if you are including a picture) Yes Section C - About the Products 1 of 1 Suspect Yes Primary? Yes Type Drug/Biologic This report is about Food/Medical food Name of the product as it WanaBana Cinnamon applesauce pouch or package (include as many names as you see) Name of the company that mediate (or compounds) the product WanaBana Product Type(check all that appear) Over-the Counter Doing the problem stop after the person started taking or using the product again? Did the problem stop after the product again? If Other Did the problem return if the product again? 25-Jun-2024 L of number Ud023 25 Did the problem return if the product again? 25-Jun-2024 L of number Ud023 25 Dow and taking or using the product again? If Other Composite adation If Other	More Information Available?			
Section B - Product Availability Do you still have the product in case we need to evaluate it? No Do you have a picture of the product? (Neek yes if you are including a picture) Yes Section C - About the Products 1 of 1 Suspect Yes Primary? Yes Type Drug/Biologic This report is about Food/Medical food Name of the product as it WanaBana Cinnamon applesauce pouch or package (include as many names as you see) Name of the company that mediate (or compounds) the product WanaBana Product Type(check all that appear) Over-the Counter Doing the problem stop after the person started taking or using the product again? Did the problem stop after the product again? If Other Did the problem return if the product again? 25-Jun-2024 L of number Ud023 25 Did the problem return if the product again? 25-Jun-2024 L of number Ud023 25 Dow and taking or using the product again? If Other Composite adation If Other	Additional Comments	1		
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Lot number 04023 25 Dosage Form Quantity If Other Frequency If Other	Drug Therapy			1 of 1
Dosage Form If Other Quantity If Other Frequency If Other	Expiration date	25-Jun-2024		
Quantity If Other Frequency If Other	Lot number	04023 25		
Frequency If Other	Dosage Form			
	Quantity		If Other	
How use it takes or used	Frequency		If Other	
now was it taken or used IT Other	How was it taken or used		If Other	

FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag es: 7

v was the person using the pr	roduct? (such as what condition was it supposed to treat)	1 of 1
Is therapy still on-going?		
Give best estimate of duration		
Date the person reduced dose of the product		
Date the person stopped taking or using the product	24-Oct-2023	
Date the person first started taking or using the product	24-Oct-2023	

Returned to Manufacturer On	
Section D - About the Medical Device	اب. اب
Name of medical device	
Name of the company that makes the medical device	
	atalog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
For implanted medical devices ONLY (such	n as pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If

Person's Initials	(b)(6)	
Sex	Male	
Gender	Cisgender man/boy	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight	9.9 kg	
Ethnicity (Choose only one)	Hispanic/Latino	

relevant)

Receipt No: F	RCT-11	77506
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37		
Race (Check all that apply)	American Indian or Alaska Native	
	Native Hawaiian or Other Pacific Islander	
	Asian	
	White	
	Black or African American	
		1
ist known medical conditions	(Such as diabetes, high blood pressure, cancer, heart disease, or others)	
N/A		
11000000		
lease list all allergies (such a	is to drugs, foods, pollen or others)	
NKDA		
Provension and the second		
st any other important inform	nation about the person (such as smoking, pregnancy, alcohol use, etc.)	
		T
st all current prescription me	dications and medical devices being used.	
		Т
st all over-the-counter medic	ations and any vitamins, minerals, supplements, and herbal remedies being used.	
		Т
ection F - About the Person I	Filling Out This Form 1 of 1	
Primary?	Yes I OF	-
	105	+
Reporter is Patient?		4
Title		

Contraction and the second second second		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	(0)(0)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	

FDA 3500B Form

Telephone number	(h)(6)	
Email address		
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	03-Nov-2023	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	



	50	1400 1400	6	U.V.	E / see padease	22.50	
acts		e 129	oteln 09 oteln 09 tamin D Omcg	you how a daily di tee.	ISE Apple puree. cinne citric acid. BLE FOR MICROWAVE	-29-2024	
- HON	o: Daokad	ans Fat 09 ans Fat 09 bissterol 0m9 dium 0m9 dium 0m9	oteln 09 oteln 09	alcium 4mg on 0.2mg otassium 60mg me % Daily Value (DV) tells avring of food contributes to	or suitable / Produced	EXP:06-25-	
	S ILO	Saturated F Trans Fat 06 Cholesterol 0 Sodium 0mg	Protein 09 Vitamin D 0	Calcium 4n Iron 0.2mg Potassium - The % Daily serving of food	Ingredients: acidulant: cit Not suitAB		
ao	2009. 2009.			<u></u>		8220	
NUSTRO1	VIIIC FL 32	lace. Once e and days. packoge h	ed under	and unces with		18	
TRUNCK BY AUST	abana bankan lite	mendary place. O mediation of a vs. mewithin 5 days.	Mid be opened und ervision. PA Free Packaging witen Free	ter more products		862118	

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FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

ontact				
ase eporter	First Name	Last Name	Email Address	Phone
(b)(6)		(b)(6)	(b)(6)	(b)(6)
ction A	- About the Problem		1). 	
	nd of problem was it? all that apply)	Used a product incorrectly Used a problem with the Had problems after switching	e effect (including new or worsening sympt which could have or led to a problem quality of the product ng from one product maker to another mak	
Date the	e problem occurred	02-Nov-2023		
Serious	1.	Yes		
(Check all that apply)		Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important me	ermanent harm	
	erious/important medical t(Please Describe Below)			
fell us w v additio	vhat happened and hov onal documents if nece	v it happened (Include ssarv)	as many details as possible l	FDA may reach out to you fo
I got he aware a novemb	r bloodwork tested last we	ek and immediately threw	on fruit pouches over the past yea out all pouches. Her lead level wa e-illne ss/investigation-elevated-le	as 16.9, and the Bill DOH is
Test Na		LEAD	Test Data	02-Nov-2023
I est Na	ine	LEAD	Test Date	UZ-INOV-2023

16.9

Test Result

Low Test Range

High Test Range

Test Unit

FDA 3500B Form

	More Information Available?					\square
100	ditional Comments					
	ditional Comments			_		
Se	ction B - Product Availability					
Γ	Do you still have the product in case we need to evaluate it?	No				Π
	Do you have a picture of the	No				\square
	product? (check yes if you are including a picture)					
197	ction C - About the Products				1 of 1	
	Suspect	Yes				
	Primary?	Yes				+
\vdash	Туре	Drug/Biologic				+
-	This report is about	Food/Medical food				+
-	Name of the product as it	WanaBana Apple Cinna	mon Fruit Puree nouch			+
	appears on the box, bottle,	Tranabana Appio Ginie				
	or package (Include as many names as you see)					
	Name of the company that	WanaBana				Н
	makes (or compounds) the product					
	Product Type(check all that	Over-the-Counter				
	apply)	Compounded by a Pharm	acy or an Outsourcing Facility			
		Generic				
	Oliveration	Biosimilar	KOther			-
-	Strength		If Other			-
-	NDC number					+
	Did the problem stop after the person reduced the dose or					
	stopped taking or using the					
\vdash	product? Did the problem return if the					+
	person started taking or using the					
D.	product again? ug Therapy			_	1 of 1	_
	Expiration date				1011	
-	Lot number					+
	Dosage Form					+
H	Quantity		If Other			+
	Frequency		If Other			+
	How was it taken or used	Oral	If Other			+
-	Date the person first started taking or using the product		200 December 20			\top
F	Date the person stopped taking					+
	or using the product					

FDA 3500B Form

Date the person reduced dose of the product			
Give best estimate of duration			
Is therapy still on-going?			
Why was the person using the p	roduct? (such as what con	dition was it supposed to treat)	1 of 1
Snack			
Returned to Manufacturer On			
Section D - About the Medical D	evice		
Name of medical device			
Name of the company that makes the medical device			
Other identifying information (Th	e model, catalog, lot, seria	I, or UDI number, and the expirat	ion date, if you can
ocate them)			
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
or implanted medical devices C	NLY (such as pacemaker	s, breast implants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
ection E - About the Person Wh	no Had the Problem		
Person's Initials	(1)(1)		
Sex	Female		
Gender	Cisgender woman/girl		
Please Specify Other Gender			
Age (specify unit of time for age)			
Date of Birth	(b)(6)		
Weight	11.25 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		1
Race (Check all that apply)	American Indian or Alaska Nativ		

FDA 3500B Form

	White Black or African American
Lis	t known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
Ple	ease list all allergies (such as to drugs, foods, pollen or others)
Lis	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
100	
LIS	at all current prescription medications and medical devices being used.
Lis	at all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
	Has now started iron supplements to increase speed in which lead will leave the body

Section F - About the Perso	n Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(G)	
Number/Street	_(b)(6)	
City		
State/Province	-	
Country	UNITED STATES	
ZIP or Postal code		
Telephone number	(b)(6)	
Email address		

Fax		
Reporter Organization		T
Department		T
Reporter Speciality		Γ
Today's date	06-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	11-Oct-2023	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I'm reporting a high lead level for my son, (b)(6), after consuming Wanna Banana pouches. During a routine wellchild exam on 10/11/23 my son recieved a finger-stick blood test that resulted in a value of 5.1. He had received a lead test the year prior that resulted in a normal range value. So this was a new diagnosis. Subsequently, we returned to the pediatrician on 10/12/23 and a venous blood draw was completed. His result was 4.3 ug/dL. We followed the pediatricians recommendations closely. We have a newer home and all toys are new as well. We keep our home clean and there are no hobby materials that could contain lead in the home. This was a mystery to us until the recent announcement regarding lead in Wanna Banana. He had actually consumed 3 packets the week prior to his testing. We have removed the remaining packets and he has not eaten any since the announcement. I also want to mention that we live in (b)(6) and travel often to [bit]. It's possible that the packets were purchased at a [bit] Dollar Tree.

Relevant Test/Laboratory Data

FDA 3500B Form

Test Name				
Tool Ivallio	BLOOD-STICK TO CHEC K LEAD LEVELS	Test Date	11-Oct-2023	
Test Result	5.1	Test Unit		
Low Test Range	0	High Test Range	3.5	
More Information Available?				
evant Test/Laboratory Data			2 of 2	
Test Name	VENOUS BLOOD-DRAW TO CHECK FOR LEAD LE VELS	Test Date	12-Oct-2023	
Test Result	4.3	Test Unit		
Low Test Range	0	High Test Range	3.5	
More Information Available?				
ction B - Product Availability				
Do you still have the product in Yes				
case we need to evaluate it?	10.000			
	No			
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture)	No		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture)	No		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect			1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect	Yes		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect Primary?	Yes Yes		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect Primary? Type	Yes Yes Drug/Biologic		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many	Yes Yes Drug/Biologic Food/Medical food		1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the	Yes Yes Drug/Biologic Food/Medical food Wanna Banana	er an Outsourcing Facility	1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) tion C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Product Type(check all that apply)	Yes Yes Drug/Biologic Food/Medical food Wanna Banana Austrofood	r an Outsourcing Facility	1 of 1	
case we need to evaluate it? Do you have a picture of the product? (check yes if you are including a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the product Product Type(check all that	Yes Yes Drug/Biologic Food/Medical food Wanna Banana Austrofood	361 04	1 of 1	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

Did the problem return if the person started taking or using the product again?			
Drug Therapy			1 of 1
Expiration date	18-Apr-2024		
Lot number	Unable to read		
Dosage Form		172	
Quantity		If Other	
Frequency		If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product		100.	
Date the person stopped taking or using the product			
Date the person reduced dose of the product			
Give best estimate of duration			
Is therapy still on-going?			
Why was the person using the pr	oduct? (such a	as what condition was it suppos	ed to treat) 1 of 1

Returned to Manufacturer On

I

Section D - About the Medical Device	
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The model, cata ocate them)	alog, lot, serial, or UDI number, and the expiration date, if you can
Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	
or implanted medical devices ONLY (such a	is pacemakers, breast implants, etc.)
Date the implant was put in	Date the implant was taken out (If relevant)

FDA 3500B Form

ection E - About the Person W	Vbo Had the Problem			
Person's Initials	(b)(6)			
Sex	Male			
Gender	Cisgender man/boy			
Please Specify Other Gender				
Age (specify unit of time for age	A			
Date of Birth	(b)(6)			
Weight	11.25 kg			
Ethnicity (Choose only one)	Not Hispanic/Latino			
Race (Check all that apply)				
Nace (Check an mar apply)	American Indian or Alaska Native			
t known medical conditions ((Such as diabetes, high blood pressure, cancer, heart disease, or others)			
Global Development Delays, Su	ispected Early Autism			
ease list all allergies (such as	s to drugs, foods, pollen or others)			
Amoxicillin				
st any other important informa	ation about the person (such as smoking, pregnancy, alcohol use, etc.)			
My son was born Preterm at 29 weeks. He is also a twin. His twin brother tested in normal ranges for lead, but did not consume as much of the Wanna Banana products as his brother.				
st all current prescription medications and medical devices being used.				
st all current prescription med	lications and medical devices being used.			
at all current prescription med Albuterol nebulizer, Triamcinolo				
Albuterol nebulizer, Triamcinolo st all over-the-counter medica				
Albuterol nebulizer, Triamcinolo	ne- both PRN			
Albuterol nebulizer, Triamcinolo st all over-the-counter medica Pediasure	ations and any vitamins, minerals, supplements, and herbal remedies being used.			
Albuterol nebulizer, Triamcinolo st all over-the-counter medica	ations and any vitamins, minerals, supplements, and herbal remedies being used.			

Title		Γ
Last name	(b)(6)	Γ
Middle Name		Γ
First name	(h)(c)	Γ
Number/Street	(b)(6)	Γ
City		Γ
State/Province		Γ
Country	UNITED STATES	Γ
ZIP or Postal code	$(\mathbf{b})(\mathbf{c})$	Γ
Telephone number	(b)(6)	Γ
Email address		Γ
Fax		Г
Reporter Organization		Γ
Department		
Reporter Speciality		Γ
Today's date	06-Nov-2023	Γ
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Receipt No: RCT-1177905 FDA 3500B Form CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact				
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	31-Oct-2023	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Child consumed Wananbana Apple Cinnamon pouch and was blood tested. Child has high level of lead on blood work

evant Test/Laboratory	Data	¥.	1 of 1
Test Name	LEAD, BLOOD (PEDS) VE NOUS	Test Date	31-Oct-2023
Test Result	4.2 high	Test Unit	GRAMS PER DECILITER
Low Test Range	0	High Test Range	3.4

More Information Available?						
Additional Comments						
Pediatric lead test on my son show	vs high level of lead.					
Section B - Product Availability				1 M		
Do you still have the product in case we need to evaluate it?	No					
Do you have a picture of the product? (check yes if you are including a picture)	No					
Section C - About the Products				1 of 1		
Suspect	Yes					
Primary?	Yes					
Туре	Drug/Biologic					
This report is about	Food/Medical food					
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wanabana Apple Ci	nnamon pouch				
Name of the company that makes (or compounds) the product						
Product Type(check all that apply)	Over-the-Counter	armacy or an Outsourcing Facility				
Strength		If Other				
NDC number						
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No					
Did the problem return if the person started taking or using the product again?	Doesn't Apply					
Drug Therapy				1 of 1		
Expiration date						
Lot number						
Dosage Form						
Quantity	Other	If Other	2 Ounce(s)			
Frequency	Other	If Other	Eat two			
How was it taken or used	Oral	If Other				
Date the person first started taking or using the product	26-Oct-2023		645			
Date the person stopped taking or using the product	27-Oct-2023					

FDA 3500B Form

Date the person reduced dose of the product	27-Oct-2023		
Give best estimate of duration			
Is therapy still on-going?			
Why was the person using the pr	oduct? (such as what co	ndition was it supposed to treat)	1 of 1
It was a snack			
Returned to Manufacturer On			
Section D - About the Medical De	avice		
Name of medical device			
Name of the company that makes the medical device			
	e model, catalog, lot, seri	al, or UDI number, and the expira	tion date, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
For implanted medical devices C	NLY (such as pacemake	rs, breast implants, etc.)	- 197 197
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person Wh	o Had the Problem		
Person's Initials	Ent.		1
Sex	Male		
Gender	Cisgender man/boy		
Please Specify Other Gender			
Age (specify unit of time for age)			
Date of Birth	(b)(6)		
Weight	16.2 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)			

	White Black or African American
ist	t known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
_	None
_	ase list all allergies (such as to drugs, foods, pollen or others)
	None
ist	t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
	None
ist	t all current prescription medications and medical devices being used.
	None
ist	t all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
_	None

Section F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	06-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-Nov-2023	CTU Received Date	07-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b)(6)	(b)(6)	(b)(6)	(b)(6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)
	Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem occurred	05-Jul-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	
	w it happened (Include as many details as possible FDA may reach out to you f ssary)
v additional documents if nece WanaBana fruit pouches were a c poisoning. We live in a new const sources of lead that our baby (b)	

(b)(6) bloodwork. We feel certain his high lead levels were a result of this dangerous product.

R	elevant Test/Laborato	ry Data		1 of 3
	Test Name	ROUTINE LEAD TEST	Test Date	05-Jul-2023
	Test Result	12.9	Test Unit	MICROGRAMS PER DEC

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

Low Test Range	0	High Test Range	5
More Information Available?			
elevant Test/Laboratory Data			2 of 3
Test Name	VENOUS BLOOD DRAW L EAD TEST	Test Date	02-Aug-2023
Test Result	13.1	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	5
More Information Available?		G.	8.
elevant Test/Laboratory Data	1 <u>.</u>	N.	3 of 3
Test Name	VENOUS BLOOD DRAW L EAD TEST	Test Date	05-Oct-2023
Test Result	8.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	5
More Information Available?			

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No	
Do you have a picture of the product? (check yes if you are including a picture)	No	

Section C - About the Product	S		1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologic		
This report is about	Food/Medical	food	
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana A	ople cinnamon fruit puree	
Name of the company that makes (or compounds) the product	WanaBana		
Product Type(check all that apply)	Compounded Generic Biosimilar	nter by a Pharmacy or an Outsourcing Facility	
Strength		If Other	
NDC number		A int	

FDA 3500B Form

Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Drug Therapy				1 of 1
Expiration date				
Lot number				
Dosage Form		10		
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product	01-Feb-2023			
Date the person stopped taking or using the product	29-Jul-2023			
Date the person reduced dose of the product	29-Jul-2023			
Give best estimate of duration				
Is therapy still on-going?				
Returned to Manufacturer On				
Section D - About the Medical De	evice			
Name of medical device				
Name of the company that makes the medical device				
Other identifying information (The locate them)	e model, catalog, k	ot, serial, or UDI number	, and the expiration d	ate, if you can
Model Number				
Catalog Number				
Lot Number				
Serial Number	0			
UDDI Number				
Expiration date				i.
Was someone operating the medical device when the problem				

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)					
Date the implant was put in	Date the implant was taken out (I relevant)	£			

Person's Initials	on's Initials (b)(6)	
Person's initials	on s iniciais	
Sex	Male	
Gender	der Cisgender man/boy	
Please Specify Other Gender	se Specify Other Gender	
Age (specify unit of time for age)	(specify unit of time for age)	
Date of Birth	of Birth (b)(6)	
Weight	ht	
Ethnicity (Choose only one)	icity (Choose only one) Not Hispanic/Latino	
Race (Check all that apply)	e (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Fill	ing Out This Form 1 of 1	
Primary?	Yes	Т
Reporter is Patient?		T
Title		t
Last name	(b)(6)	t
Middle Name		t
First name	$(\mathbf{h})(\mathbf{c})$	t
Number/Street	(b)(6)	t
City	$(\sim)(\circ)$	t
State/Province		t
Country	UNITED STATES	t
ZIP or Postal code	$(\mathbf{b})(\mathbf{c})$	t
Telephone number	(b)(6)	t
Email address		t
Fax		t
Reporter Organization		t
Department		t
Reporter Speciality		t
Today's date	07-Nov-2023	t
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pag es: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details						
Company Unit	CDER-CTU	Originating Account	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority	Routine	Routine				
Override Auto Calculation Rule	No					
FDA Received Date	07-Nov-2023	CTU Received Date	07-Nov-2023			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User					
User/Group						
Forward to Department	CDER (CDER-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct					

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		

Sect	tion A - About the Problem		
	What kind of problem was it? Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
1	Date the problem occurred	07-Nov-2023	
5	Serious	No	
	Did any of the following happen? Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident/Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

https://www.fda.gov/food/outbreaks-foodborne-illne ss/investigation-elevated-lead-levels-applesauce-p ouchesnovember-2023#contact Our 18 month old son ate quite a few of these and has lead levels of 4.8. We just wanted to report this as recommended. It was the WanaBana apple cinnamon pouches. We threw out any we had of the brand just in case.

evant Test/Laboratory	Data	10	1 of 1
Test Name	LEAD BLOOD TEST	Test Date	07-Nov-2023
Test Result	4.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	<3.5	High Test Range	>3.5

FDA 3500B Form

More Information Available?				
Additional Comments				
Section B - Product Availability				
Do you still have the product in case we need to evaluate it?	No			
Do you have a picture of the product? (check yes if you are including a picture)	No			
Section C - About the Products				1 of 1
Suspect	Yes			
Primary?	Yes			
Туре	Drug/Biologic			
This report is about	Food/Medical food			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple cinna	mon		
Name of the company that makes (or compounds) the product	WanaBana			
Product Type(check all that apply)	Over-the-Counter	acy or an Outsourcing Facilit	e e e e e e e e e e e e e e e e e e e	
Strength		If Other		
NDC number				
Did the problem stop after the person reduced the dose or stopped taking or using the product?				
Did the problem return if the person started taking or using the product again?	9			
Drug Therapy				1 of 1
Expiration date				1
Lot number				
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		
Date the person first started taking or using the product				
Date the person stopped taking or using the product				

FDA 3500B Form

Date the person reduced dose of the product			
Give best estimate of duration	3 Month		
Is therapy still on-going?			
	roduct? (such as what co	indition was it supposed to treat)	1 of 1
Food			
Returned to Manufacturer On			
ection D - About the Medical De	evice		
Name of medical device			
Name of the company that makes the medical device			
	e model, catalog, lot, ser	ial, or UDI number, and the expiral	ion date, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?			
or implanted medical devices O	NLY (such as pacemake	ers, breast implants, etc.)	
ate the implant was put in		Date the implant was taken out (If relevant)	
ection E - About the Person Wh	no Had the Problem		
Person's Initials	(b)(6)		
Sex	Male		
Gender	Cisgender man/boy		
Please Specify Other Gender			
Age (specify unit of time for age)	18 Month(s)		
Date of Birth			
Weight	9.9 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Na		

	White Black or African American	
Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Γ		٦
Pk	ease list all allergies (such as to drugs, foods, pollen or others)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis		
Lis	st all current prescription medications and medical devices being used.	

ection F - About the Perso	on Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street	(n)(n)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(h)(c)	
Telephone number	(b)(6)	
Email address		

Fax		
Reporter Organization		T
Department		T
Reporter Speciality		Т
Today's date	07-Nov-2023	Т
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pag es: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Nov-2023	CTU Received Date	08-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	Contact					
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Γ	Date the problem occurred	28-Oct-2023	
Г	Serious	No	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My infant consumed 2 pouches of wanabana apple cinnamon and now has a lead level of 13ug/dL. Child appears healthy at this time. Pouches were eaten on October 37 and 28. Test was run Oct 31, results received that Friday. As of Nov 3rd pouches were still being sold. When I told the manager, they removed them from shelves but said there had been no message from corporate (dollar tree) Lot:10022 19 19

elevant Test/Laboratory Data			1 of 1
Test Name	BLOOD LEAD TEST, VEN OUS	Test Date	31-Oct-2023
Test Result	13	Test Unit	MICROGRAMS PER DEC
Low Test Range		High Test Range	

FDA 3500B Form

More Information Available?					
ditional Comments					
ection B - Product Availability					
Do you still have the product in case we need to evaluate it?	Yes				
Do you have a picture of the product? (check yes if you are including a picture)	Yes				
ection C - About the Products				1 of 1	1
Suspect	Yes				- 1
Primary?	Yes				
Туре	Drug/Biologic				
This report is about	Food/Medical food	d			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wanabana apple	cinnamon fruit purée			
Name of the company that makes (or compounds) the product					
Product Type(check all that apply)	Over-the-Counter	Pharmacy or an Outsourcing Fi	acility		
Strength		If Other			
NDC number					
Did the problem stop after the person reduced the dose or stopped taking or using the product?					
Did the problem return if the person started taking or using the product again?	Doesn't Apply				
ug Therapy				1 of	1
Expiration date	31-Dec-2023				
Lot number	10022 19 19				
Dosage Form					
Quantity		If Other			
Frequency		If Other			
How was it taken or used		If Other			
Date the person first started taking or using the product	27-Oct-2023	West .			
Date the person stopped taking or using the product	28-Oct-2023				

FDA 3500B Form

Date the person reduced dose of the product			
Give best estimate of duration			
Is therapy still on-going?			
	roduct? (such as what c	ondition was it supposed to treat)	1 of 1
Food			
Returned to Manufacturer On			
ection D - About the Medical De	evice		
Name of medical device	3108		
Name of the company that makes the medical device			
	e model, catalog, lot, se	rial, or UDI number, and the expira	tion date, if you can
Model Number	1		
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem occurred?	h		
or implanted medical devices O	NLY (such as pacemak	ers, breast implants, etc.)	1 1
ate the implant was put in		Date the implant was taken out (If relevant)	
ection E - About the Person Wh	no Had the Problem		5-
Person's Initials	(b)(6)		
Sex	Male		
Gender	Cisgender man/boy		
Please Specify Other Gender			
Age (specify unit of time for age)	7 Month(s)		
Date of Birth			
Weight	8.775 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska N		

es: 7		
	White Black or African American	
List known medical condit	ions (Such as diabetes, high blood pres	sure, cancer, heart disease, or others)
None		
	ich as to drugs, foods, pollen or others)	
None		
List any other important ir	formation about the person (such as sm	oking, pregnancy, alcohol use, etc.)
List all current prescription	n medications and medical devices being	g used.
None		
List all over-the-counter n	edications and any vitamins, minerals,	supplements, and herbal remedies being used.
None		

Section F - About the Person	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(h)(c)	
Number/Street	(b)(6)	
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	$(l_{r})(c)$	
Telephone number	(b)(6)	
Email address	$(\sim)(\circ)$	

Fax		Γ
Reporter Organization		T
Department		T
Reporter Speciality		Г
Today's date	08-Nov-2023	Г
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Av. Gral. Enriquez V Av. Gral. Enriquez V Jochi (Esq.), Quito Ecuador. Ted in USA by: Wanaban^a fanabana USA, LLC 2113 W. eet - Jacksonville FL 32209. (0DE: 0032-BPM-AN-0818 e: 888-272-7184 19 INEN 2337

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Luod L

Del

Serving per package

Serving Size:

NULTITION

Amount per serving

Calories

%0 %0

Saturated Fat 0g

Total Fat 0g

Cholesterol 0mg

Sodium Omg

Trans Fat 0g

ent

% Daily

%0

%0

4% 2%

Total Carbohydrate 129

Dietary Fiber 29 Total Sugars 99

ein cool dry place. Once ned, refrigerate and sume within 5 days.

shipe opened under adult product's cap This package has a sn ap. This -Unitations :DW

- Hee Packaging
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* The % Daily Value (DV) tells you how much a nutrient ina Potassium 60mg

0%0 %0 0/00

%0

%0

Includes 0g Added Sugars

Vitamin D 0mcg Calcium 4mg

Protein 0g

Iron 0.2mg

serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder, acidulant: citric acid.

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Batch Nº / Produced / Best by / see package NOT SUITABLE FOR MICROWAVE

