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-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

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	25-Jun-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)

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.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD TEST FINGER POKE	Test Date	27-Jun-2023	
Test Result	8.6	Test Unit	MICROGRAMS PER DECILITRE	

	Low Test Range		High Test Range		
	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			
	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 APPLE CINNAMON			
	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?	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-Dec-2022			

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?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Female
Gender	Not selected
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	8.55 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.

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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b)(6)
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	08-Dec-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	

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

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	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)

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 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 1 of 4

Test Name	LEAD SCREEN (SON)	Test Date	27-Jul-2023

Test Result	8.5mcg/dl	Test Unit	MILLIGRAMS PER DECILITRE	
Low Test Range	0.0	High Test Range	4.9	
More Information Available?				

Relevant Test/Laboratory Data 2 of 4

Test Name	LEAD, VENOUS (SON)	Test Date	31-Jul-2023
Test Result	6.8mcg/dl	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.0	High Test Range	4.9
More Information Available?			

Relevant Test/Laboratory Data 3 of 4

Test Name	LEAD SCREEN (SON)	Test Date	25-Oct-2023
Test Result	<3.3mcg/dl	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.0	High Test Range	4.9
More Information Available?			

Relevant Test/Laboratory Data 4 of 4

Test Name	LEAD, VENOUS (MOTHER)	Test Date	10-Nov-2023
Test Result	0.0mcg/dl	Test Unit	MILLIGRAMS PER DECILITRE
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

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 appears on the box, bottle, or package (Include as many names as you see)	Apple Cinnamon Fruit Puree

	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			
	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		
	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 product? (such as what condition was it supposed to treat) 1 of 1

It is baby food.

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 ☐ 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.)

He is an infant.

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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	11-Dec-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

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/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)	

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	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)

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 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.

Relevant 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?			

Relevant Test/Laboratory Data 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?				

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			
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 Apple Cinnamon Fruit Puree			
Name of the company that 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 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	01-Oct-2022			
	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?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	for food

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

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)	☐ 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)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number		
	Email address	(b)(6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	13-Dec-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	

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-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

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	29-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 ☐ 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 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/Laboratory 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 Available?			

Relevant Test/Laboratory 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 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		
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		
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?	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	

	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?				

Why was the person using the product? (such as what condition was it supposed to treat)	1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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

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	
City	
State/Province	

	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	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)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Baby loves this babyfood eat every feeding after breast milk

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)	
Sex	Male	
Gender	Not selected	
Please Specify Other Gender		
Age (specify unit of time for age)		
Date of Birth	(b)(6)	
Weight	6.75 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)

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.)

NA

List all current prescription medications and medical devices being used.

Amoxicillin 400mg Poly-vitamin/w iron solution

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

NA

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	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)?	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	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)

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	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)	

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 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.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD, WHOLE BLOOD	Test Date	01-Jun-2023	
Test Result	<1.0	Test Unit	MICROGRAMS PER DECILITRE	

Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data 2 of 2

Test Name	LEAD, WHOLE BLOOD	Test Date	16-Nov-2023
Test Result	2.1	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	
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		
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)	Wananana Apple Cinnamon Fruit Puree		
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?			
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				
	Give best estimate of duration				
	Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat)	1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	[redacted]
	Sex	Male
	Gender	Not selected

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)

	Number/Street		
	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number	(b)(6)	
	Email address		
	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)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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	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-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

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-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)	

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

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD TEST	Test Date	28-Nov-2023	
Test Result	8.0	Test Unit	MICROGRAMS PER DECILITRE	

	Low Test Range	0	High Test Range	3.5	
	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			
	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 pouches			
	Name of the company that 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 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	01-Jan-2023			

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 product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

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 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 ☐ 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	28-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	

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	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	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	01-Nov-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)

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)

Daughter consumed a recalled product and lead was found in her blood - level 7.

Relevant Test/Laboratory Data 1 of 1

Test Name	PEDIATRIC LEAD SCREENING	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?			

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		
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)	Apple Cinnamon Puree		
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			
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			

Give best estimate of duration	2 Month	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Transition to solid foods

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section 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	9 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)
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

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		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number		
Email address		
Fax		
Reporter Organization		

	Department		
	Reporter Speciality		
	Today's date	29-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	

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	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	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	06-Nov-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)

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 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.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD, CAPILLARY	Test Date	06-Nov-2023
Test Result	11	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	3

	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		
	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 Apple Cinnamon Fruit Puree		
	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?			
	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	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		

	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Snack

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 ☐ 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.)

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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	29-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	

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	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	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	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)	

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 2 year old ate the Wana Bana applesauce pouches purchased from Dollar Tree in (b)(6) and had an 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.

Relevant Test/Laboratory Data 1 of 1

Test Name	BLOOD LEAD LEVEL	Test Date	04-Nov-2023
Test Result	6.7	Test Unit	GRAMS PER DECILITER

	Low Test Range		High Test Range		
	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			
	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)	Cinnamon applesauce			
	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?				
	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	11-Jul-2023			

	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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	29-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	

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	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	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)	

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)

Consumed 4 Wanabana cinnamon pouches. Confirmed elevated blood lead level.

Relevant Test/Laboratory Data 1 of 1

	Test Name	VENOUS BLOOD LEAD TEST	Test Date	08-Nov-2023
	Test Result	13.6	Test Unit	MILLIGRAMS PER DECILITRE

	Low Test Range		High Test Range		
	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			
	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 apple cinnamon fruit puree			
	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?				
	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	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 taking or using the product	24-Oct-2023			

Date the person stopped taking or using the product	24-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 product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	[redacted]
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	5 Year(s)
Date of Birth	
Weight	18.9 kg
Ethnicity (Choose only one)	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)

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

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	
City	
State/Province	(b)(6)
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	29-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	

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-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-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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	
	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 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?			

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		
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 Apple Cinnamon Fruit Puree Pouches		
Name of the company that 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 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			

	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	[redacted]
	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 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	30-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	

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

	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-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)	

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 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.

Relevant 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?	

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)	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 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 ☐ 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 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		
	Give best estimate of duration		
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	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	
	Ethnicity (Choose only one)	
	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.)

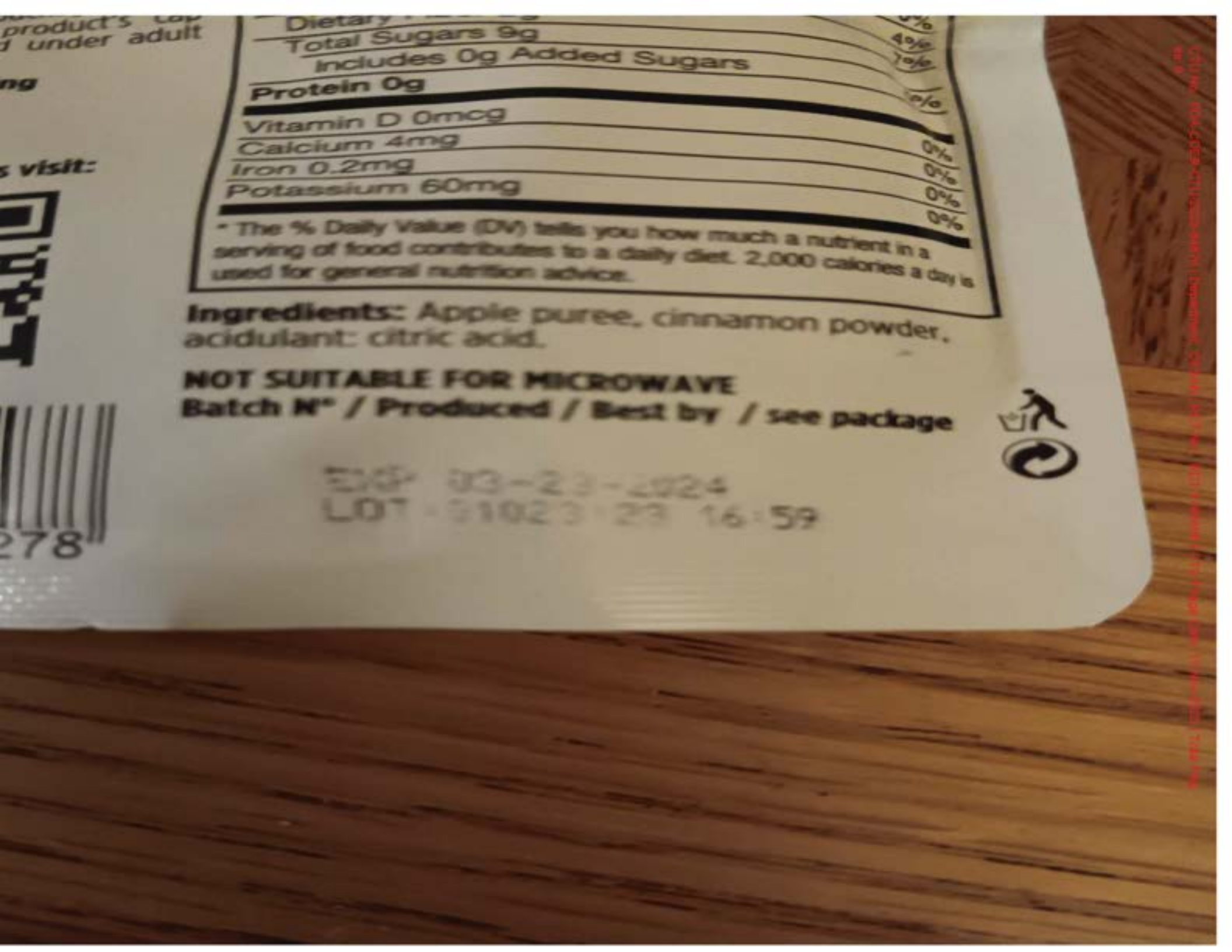
List all current prescription medications and medical devices being used.

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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	01-Dec-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	



product's cap
under adult

visit:

278

Dietary	0%
Total Sugars 9g	4%
Includes 0g Added Sugars	1%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

EXP 03-23-2024
LOT 231023 23 16:59

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

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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	25-Oct-2023
Date of this Report	17-Nov-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Child's mother reports that she purchased the Wana Bana brand of Apple Cinnamon Fruit Puree from Dollar Tree around 10/23/23. Mother reports that she purchased a three pouch pack of the product from the Dollar Tree located at either (b)(6) . Mother states she shops at both locations but can't remember which location she purchased this product from. Mother can't remember exact dates her child consumed the three pouches of puree but upon hearing the recall information on the news mother contacted her child's pediatrician to arrange for a blood test. The pediatrician's office contacted the health department via phone on 11/13/23 to report child's elevated blood lead level and report that the child was tested because the mother reported that she had consumed the puree.

Relevant Test/Laboratory Data 1 of 1

Test Name	VENOUS BLOOD LEAD TEST	Test Date	08-Nov-2023
Test Result	7.9	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	> 3.5 mcg/dL
More Information Available?			

Additional Comments

Child had previously been tested for lead in March 2023 and did not have an elevated blood lead level.

Other Relevant History, Including Preexisting Medical Conditions

No pre-existing health conditions reported by mother.

C. 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

D. PRODUCT(S) 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Wana Bana Apple Cinnamon Fruit Puree

	Strength	233 G gram(s)	If Other		
	Manufacturer/Compounder	Wana Bana			
	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			

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

E. SUSPECT MEDICAL DEVICE

	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	
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

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

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	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 ☐ 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)

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.

Relevant Test/Laboratory Data				1 of 4
Test Name	LEAD CAPILLARY	Test Date	20-Sep-2023	
Test Result	21.5	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				2 of 4
Test Name	LEAD BLOOD VENOUS	Test Date	28-Sep-2023	
Test Result	21.0	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				3 of 4
Test Name	XR ABDOMEN	Test Date	02-Oct-2023	
Test Result	Large amount of stool throughout the colon.	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Relevant Test/Laboratory Data				4 of 4
Test Name	LEAD BLOOD VENOUS	Test Date	25-Oct-2023	
Test Result	25.4	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section 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

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 appears on the box, bottle,	WanaBana apple cinnamon fruit Puree pouches

	or package (Include as many names as you see)			
	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?	Yes		
	Did the problem return if the person started taking or using the product again?	Yes		

Drug 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		
	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		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Hunger/nutrition

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	[redacted]
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.

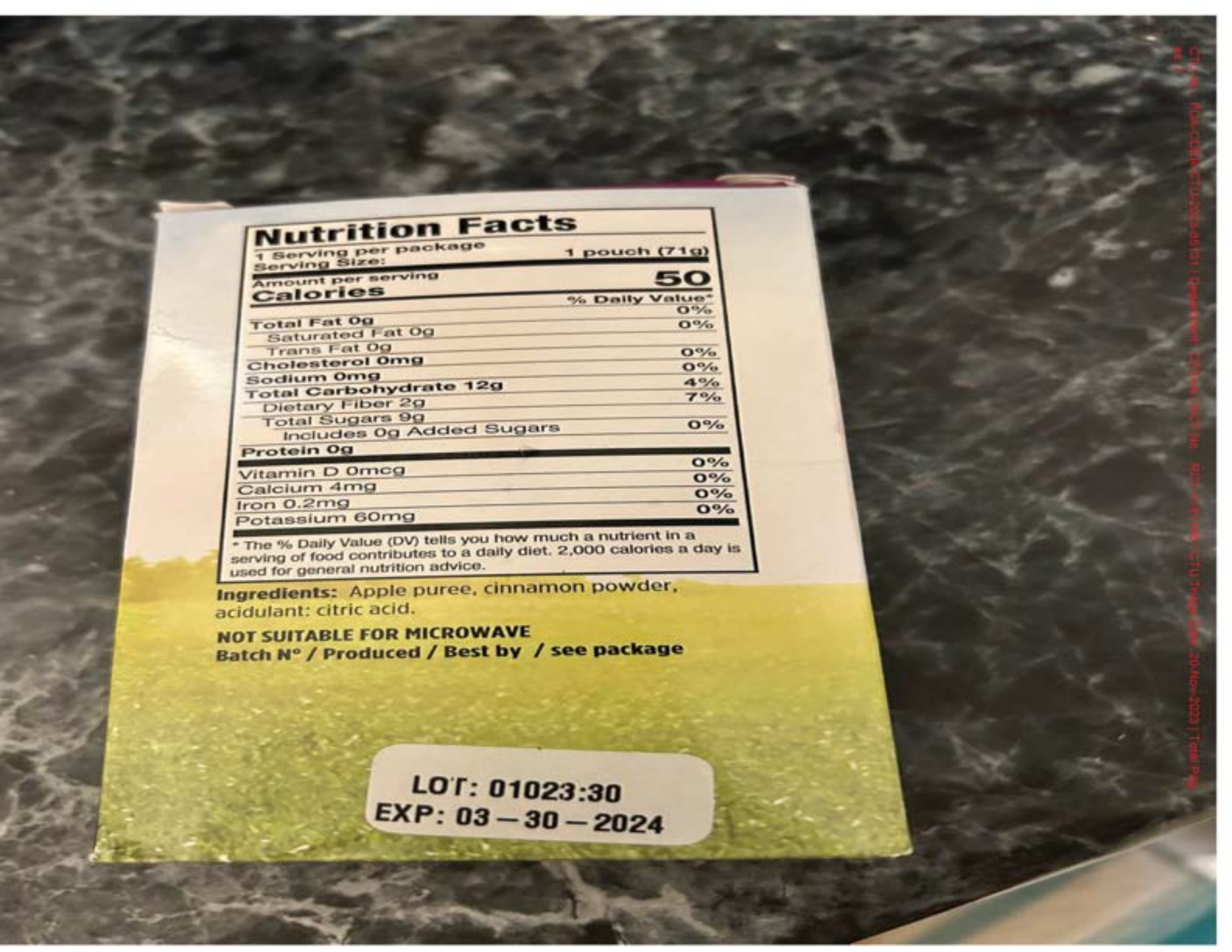
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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


KOSHER
NO SUG
ADDE
Net Weight:
7.50 oz
(213 g)
WANA BANA®
APPLE
CINNAMON
FRUIT PUREE
•No preservatives
•Gluten free
3
PACK



Nutrition Facts

1 Serving per package
Serving Size: 1 pouch (71g)

Amount per serving
Calories 50

	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 2g	7%
Total Sugars 9g	
Includes 0g Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

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	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)

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	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)	

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 daughter, (b)(6) (now 15.5 month old), was gifted approximately 6 WanaBana apple cinnamon fruit puree pouches on 08/05/2023. She consumed these over the next few weeks. At her 12-month well child check on 08/23/2023, she had her blood lead level checked. Her first toe prick (capillary) BLL result was 6.2 ug/dL, and it was confirmed by a second toe prick on the same day. To verify accuracy, she had a repeat BLL done by venous draw on 08/24/2023, with a result of 6.4 ug/dL. We live in a house built in 1952, so we assume it was an issue with our home. Our water testing came back negative for lead. Our paint testing came back with few areas of concern (and most did not have deteriorating paint prior to testing). We assumed the lead must have been present in some sort of baby food, or baby toy, as my husband and my own BLL tests came back negative as well. Everything clicked when we saw the recall alert for WanaBana apple cinnamon fruit puree pouches with our local news station. Luckily, our 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 1 of 3

	Test Name	LEAD, BLOOD (PEDS) CAPILLARY (IN-HOUSE)	Test Date	23-Aug-2023	
	Test Result	6.2	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL	
	More Information Available?				

Relevant Test/Laboratory Data 2 of 3

	Test Name	LEAD, BLOOD (PEDS) VENOUS	Test Date	24-Aug-2023	
	Test Result	6.4	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL	
	More Information Available?				

Relevant Test/Laboratory Data 3 of 3

	Test Name	LEAD, BLOOD (PEDS) VENOUS	Test Date	30-Oct-2023	
	Test Result	2.2	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL	
	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
	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 apple cinnamon fruit puree pouches
	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?				
	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	05-Aug-2023			
	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 product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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 ☐ Asian ☑ White ☐ Black or African American

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.

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 Identifier (In Confidence)	(b)(6)
Age	
Date of 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 ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	13-Oct-2023
Date of this Report	20-Nov-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient consumed 2 pouches per day of Wana Bana apple cinnamon fruit pouches from April 2023 through September 2023. The fruit pouches were purchased at Dollar Tree. Venous blood lead testing was done 10/13/2023 and the blood lead level was elevated.

Relevant Test/Laboratory Data

1 of 1

Test Name	VENOUS BLOOD LEAD LEVEL	Test Date	13-Oct-2023
Test Result	11.3	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	3.4
More Information Available?			

Additional Comments

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	
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		
Type	Drug/Biologic		
This report involves:	Food/Medical food		

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Wana Bana Apple Cinnamon Fruit Puree Pouches		
Strength		If Other	
Manufacturer/Compounder	Wana Bana		

	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	180 G gram(s)	If Other		
	Frequency	Daily	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

E. SUSPECT MEDICAL DEVICE

	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	

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	(b)(6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b)(6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Nurse	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	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	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)

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	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)

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)

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

Relevant Test/Laboratory Data 1 of 6

	Test Name	LEAD,VENOUS	Test Date	06-Nov-2023
	Test Result	10.4	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range		High Test Range	

	More Yi'brmation Available?				
Relevant Test/Laboratory Data					2 o1l
	Test Name	LEADx6ENOUS	Test Date	14-Nov-2023	
	Test Result	7	Test Unit	MYLLYGRAMS PER DECYL YTRE	
	Lof Test Range		High Test Range		
	More Yi'brmation Available?				
Relevant Test/Laboratory Data					3 o1l
	Test Name	HEMATOCRYT	Test Date	14-Nov-2023	
	Test Result	28v8	Test Unit	PERCENT	
	Lof Test Range		High Test Range		
	More Yi'brmation Available?				
Relevant Test/Laboratory Data					4 o1l
	Test Name	HEMATOCRYT	Test Date	03-Nov-2023	
	Test Result	32w	Test Unit	PERCENT	
	Lof Test Range		High Test Range		
	More Yi'brmation Available?				
Relevant Test/Laboratory Data					5 o1l
	Test Name	HEMOGLOBYN	Test Date	03-Nov-2023	
	Test Result	11	Test Unit	GRAMS PER DECYLYTER	
	Lof Test Range		High Test Range		
	More Yi'brmation Available?				
Relevant Test/Laboratory Data					I o1l
	Test Name	HEMOGLOBYN	Test Date	14-Nov-2023	
	Test Result	10v2	Test Unit	GRAMS PER DECYLYTER	
	Lof Test Range		High Test Range		
	More Yi'brmation Available?				

Additional Comments

Section B - Product Availability

	Do you still have the product in case f e need to evaluate it?	No
	Do you have a picture o1the product? (check yes i1you are including a picture)	No

Section C - About the Products 1 o11

	Suspect	Yes			
	Primary?	Yes			
	Type	Drug/Biologic			
	This report is about	Food/Medical 'bod			
	Name o1the product as it appears on the bo4xbottlex or package (Yiclude as many names as you see)	Wana bana cinnamon apple puree 3 pack			
	Name o1the 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		YlOther		
	NDC number				
	Did the problem stop a1ter 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?				

Drug Therapy 1 o11

	E4piration date				
	Lot number				
	Dosage Form				
	Vuantity		YlOther		
	Frequency		YlOther		
	Hof f as it taken or used	Oral	YlOther		
	Date the person 1rst started taking or using the product	25-Sep-2023			
	Date the person stopped taking or using the product	20-Oct-2023			
	Date the person reduced dose o1 the product				
	Give best estimate o1duration				
	Ys therapy still on-going?				

Why f as the person using the product? (such as f hat condition f as it supposed to treat) 1 o11

	Returned to Manu1acturer On	

Section D - About the Medical Device

	Name o1medical 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 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 out (If relevant)	

Section 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	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 ☐ 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.

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		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number		
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	

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 Identifier (In Confidence)	(b)(6)
Age	21 Month(s)
Date of Birth	
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Weight	10.2 kg
Ethnicity (Check single best answer)	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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	15-Nov-2023
Date of this Report	20-Nov-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Ares ate apple sauce with cinnamon that was made by wanabana and was part of the recall. he has an elevated lead level

Relevant Test/Laboratory Data

1 of 1

Test Name	LEAD	Test Date	15-Nov-2023
Test Result	10.9	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	3.4
More Information Available?			

Additional Comments

venous draw

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	
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
Type	Drug/Biologic
This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	wanabana applesauce with cinnamon		
Strength		If Other	
Manufacturer/Compounder			

	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			

Drug 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?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	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	

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	(b)(6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b)(6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Physician	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	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	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		

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	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)

My 5 year old ate 14 pouches of the wanabana applesauce within 2 weeks before I was aware of the recall on Oct 31st. He had been sick, headache, stomach ache, tired, lethargic, not eating, and just felt horrible. I had him lead tested and his lead was 12.2.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD TEST	Test Date	31-Oct-2023
Test Result	12.2	Test Unit	UNKNOWN
Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Health department came and we have no other source of contamination. We live in a house built in 2009, he doesn't have access to any lead paint.

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Wanabana Apple cinnamon applesauce pouch			
	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	23-Jun-2024			
	Lot number	0402323			
	Dosage Form				
	Quantity	Other	If Other	14 Pouches	
	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	15-Oct-2023			
	Date the person stopped taking or using the product	31-Oct-2023			

Date the person reduced dose of the product	31-Oct-2023	
Give best estimate of duration		
Is therapy still on-going?	Yes	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Food he likes to eat

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 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 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)

Autism level 2

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.)

Dev. Delays

List all current prescription medications and medical devices being used.

Guanfacine

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

Polyvisol

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	


WANA BANA
No preservatives
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz

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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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	19-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)	

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)

CFSAN CAERS PHONE REPORT 24-NOV-2023:My name is (b)(6). I purchased a Wanabana Apple Cinamon, November 19 from Dollar Tree. Immediately after, I had a reaction. My adverse reaction included: allergic reaction, hives on my face and itchy. I continue to experience these symptoms and they are getting worse. This product is recalled, I don't know where to go about this, I believe there is lead in my system.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section B - Product Availability

	Do you still have the product in case we need to evaluate it?	
	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		
	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 APPLE CINAMON PAUCH		
	Name of the company that 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 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	19-Nov-2023		
	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 product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Not selected
	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)	☐ 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)
Number/Street	
City	
State/Province	--
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b)(6)
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	24-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

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

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	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)

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 kid's lead levels are elevated because of the Wana Bana applesauce. She's not in any danger, but they are elevated.

Relevant Test/Laboratory Data 1 of 1

	Test Name	LEAD	Test Date	10-Nov-2023
	Test Result	Slightly elevated	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

I don't have a copy of the test, pretty sure it was in the 18 range but don't remember anything except that it's slightly elevated and to feed her calcium and retest in a month.

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		
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)	Cinnamon Applesauce		
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			
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	Other	If Other	3 Pouch
Frequency	As needed	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			

Give best estimate of duration	3 Month	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Food

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section 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	15.75 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)
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.

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	
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)?	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	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

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	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 ☐ 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)

child tested for elevated lead levels related to wanabana fruit pouches

Relevant Test/Laboratory Data 1 of 2

	Test Name	LEAD LEVEL	Test Date	27-Oct-2023
	Test Result	6.8	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range	0	High Test Range	3.5

	More Information Available?				

Relevant Test/Laboratory Data 2 of 2

	Test Name	LEAD LEVEL	Test Date	17-Nov-2023	
	Test Result	4.3	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0	High Test Range	3.5	
	More Information Available?				

Additional Comments

lead level improved with removal 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			
	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	manufactured by - Austrofood			
	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?	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-Jan-2023			
	Date the person stopped taking or using the product	26-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 product? (such as what condition was it supposed to treat) 1 of 1

it is a snack for children - in her lunch

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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	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 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	

	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number	(b)(6)	
	Email address		
	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)?	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	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

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-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)

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 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 grandmother contacting saying they seen the recall on the news. I've been to the hospital several times unaware of why my baby kept being sick vomiting, belly aches, irritable 10/16/2023, 11/08/2023, and 11/16/2023. The doctor was concerned about his weight loss. November 16,2023 was his well check with his pediatrician (b)(6) she later called 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/Laboratory Data 1 of 1

Test Name	CBC(PLATELETS) LEAD BLOOD COMPLETE AS DIRECTED	Test Date	16-Nov-2023
Test Result		Test Unit	

	Low Test Range		High Test Range	Lead poisioning	
	More Information Available?				

Additional Comments

I will be getting his MyChart results Monday 11/27/2023 December 13,2023 for lead level check and well check

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			
	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 apple cinnamon fruit puree pouch			
	Name of the company that makes (or compounds) the product	Weis, WanaBana, Schnucks			
	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	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			

	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)	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 appears on the box, bottle, or package (Include as many names as you see)	Apple cinnamon fruit puree		
	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			
	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		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		

	Date the person reduced dose of the product		
	Give best estimate of duration		
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Favorite apple sauce

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 age)	
	Date of Birth	(b)(6)
	Weight	16.65 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ 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.)

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.

Cilantro heavy metal detox

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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	

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	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-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

	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	29-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)

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 son has consumed some apple puree packages and isn't feeling too well. Vomiting and has 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.

Relevant Test/Laboratory Data 1 of 1

	Test Name	LEAD PANEL	Test Date	09-Nov-2023	
	Test Result	Positive for lead	Test Unit		
	Low Test Range		High Test Range		
	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)	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 appears on the box, bottle, or package (Include as many names as you see)	Cinnamon Apple Puree		
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?			

Drug Therapy 1 of 1

Expiration date	09-Jul-2024		
Lot number	05023:09		
Dosage Form			
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			

Give best estimate of duration		
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

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 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 ☐ 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)
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 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		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number		
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	

al Fat 0g	0%
turated Fat 0g	
ans Fat 0g	0%
esterol 0mg	0%
um 0mg	4%
Carbohydrate 12g	7%
ary Fiber 2g	
l Sugars 9g	0%
cludes 0g Added Sugars	
n 0g	
D 0mcg	0%
n 4mg	0%
mg	0%
um 60mg	0%

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

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-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

	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-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)	

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 daughter received a blood test with results of abnormal levels of lead in her blood. She has been more irritable and cranky.

Relevant 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	

	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		
	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	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			
	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	07-Oct-2022		
	Date the person stopped taking or using the product	15-Feb-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 product? (such as what condition was it supposed to treat) 1 of 1

	Good pick pouch

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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	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.

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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	

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	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-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

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	08-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)		

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 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.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD	Test Date	11-Nov-2023	
Test Result	4	Test Unit	MICROGRAMS PER DECILITRE	

Low Test Range	0.0	High Test Range	3.4	
More Information Available?				

Relevant Test/Laboratory Data 2 of 2

Test Name	LEAD	Test Date	08-Aug-2023
Test Result	2	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0.0	High Test Range	3.4
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		
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)	Wanna bana fruit puree pouchedls		
Name of the company that 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 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	01-Feb-2023			
	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?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Male
	Gender	Not selected

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 ☐ 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)

	Number/Street		
	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	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	

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:	[redacted]	
A2. Age:	2	Year(s)
A2. Date of Birth:		
A3a. Sex: Enter the patient's sex at birth	Male	Yes
	Female	
	Undifferentiated	
	Decline to answer	
A3b. Gender: Enter the patient's current gender	Cisgender man/boy (gender corresponds with birth sex)	
	Cisgender woman/girl (gender corresponds with birth sex)	
	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:		
A5. Ethnicity:	Hispanic/Latino	
	Not Hispanic/Latino	Yes
A6. Race:	Asian	
	American Indian or Alaskan Native	
	Black or African American	
	White	Yes
	Native Hawaiian or Other Pacific Islander	

B. ADVERSE EVENT, PRODUCT PROBLEM		
B1. Type of Report:	Adverse Event	
	Product Use/Medication Error	
	Product Problem (e.g., defects/malfunctions)	Yes
	Problem with Different Manufacturer of Same Medicine	
B2. Outcome Attributed to Adverse Event:	Death *(Date of Death)*	
	Life-threatening	
	Hospitalization (initial or prolonged)	
	Disability or Permanent Damage	
	Congenital Anomaly/Birth Defects	
	Other Serious or Important Medical Events	Yes
	Required Intervention to Prevent Permanent Impairment/Damage	
B3. Date of Event:	25-Oct-2023	
B4. Date of this Report:	15-Nov-2023	

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

Child had an elevated blood lead level of 9.1 per venous draw on 10/25/23. Mother 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 dollar tree. Mother estimates child was sometimes eating up to two to three packs of the fruit puree per day.

B6. Relevant Tests/Laboratory Data:	
Test 1	
Test Date:	25-Oct-2023
Test Name:	venous lead level
Test Result:	9.1
Test Unit:	UG/DL
Low Test Range:	0
High Test Range:	
Test 2	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
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:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

B6. Relevant Tests/Laboratory Data:	
Test 5	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 6	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 7	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
Test 8	
Test Date:	
Test Name:	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	

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 Elevated blood lead level could be environmental. Plan to recheck 3 months from last date to see if lead level decreases since child has stopped eating the applesauce

C. PRODUCT AVAILABILITY	
C1. Product Available for Evaluation?	No
C1. Returned to Manufacturer on:	
C2. Do you have a picture of the product?	

D. SUSPECT PRODUCTS						
Product 1						
D1. This report involves:	Cosmetic					
	Dietary supplement					
	Food/medical food	Yes				
	Other					
D1. Name:	WanaBana Apple Cinnamon Fruit Puree pouches					
D1. Strength:						
D1. Manufacturer/Compounder:						
D1. NDC # or Unique ID:						
D1. Lot #:						
D2. Dose or Amount:						
D2. Frequency:						
D2. Route:						
D3. Treatment Dates/Therapy Dates:	Start		Stop		Dose Reduced	
	Give best estimate of duration					
	Is therapy still on-going?					
D4. Diagnosis for Use:						
D5. Product Type:	OTC (Over-the-counter)					
	Compounded					
	Generic					
	Biosimilar					
D6. Expiration Date:						
D7. Event Abated After Use Stopped or Dose Reduced?	Doesn't apply					
D8. Event Reappeared After Reintroduction?	Doesn't apply					
Product 2						
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:						
D3. Treatment Dates/Therapy Dates:	Start		Stop		Dose Reduced	
	Give best estimate of duration					
	Is therapy still on-going?					
D4. Diagnosis for Use:						
D5. Product Type:	OTC (Over-the-counter)					
	Compounded					
	Generic					
	Biosimilar					
D6. Expiration Date:						
D7. Event Abated After Use Stopped or Dose Reduced?						
D8. Event Reappeared After Reintroduction?						

E. SUSPECT MEDICAL DEVICE			
E1. Brand Name:	WanaBana Apple Cinnamon Fruit Puree pouches		
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		
	Other		
E6a. If Implanted, Give Date:			
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?			

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product Name	Therapy Start Date	Therapy End Date
1. WanaBana Apple Cinnamon Fruit Puree pouches		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		
21.		

G. REPORTER		
G1. Name and Address	Last Name	(b)(6)
	First Name	
	Address	
	City	(b)(6)
	State/Province/Region	
	ZIP/Postal Code	
	Country	US
	Phone #:	(b)(6)
	Email:	
G2. Health Professional?	Yes	
G3. Occupation:	Nurse	
G4. Also Reported To:	Manufacturer/Compounder	
	User Facility	
	Distributer/Importer	
G5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in 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	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

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)

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 son has been consuming WanaBana Cinnamon Fruit Puree Pouches over the last several months. I heard about the recall and called his doctor, who had him go for blood work. The results show an elevated level of lead in his blood.

Relevant 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 DECILITRE
Low Test Range		High Test Range	

	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		
	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 Apple Cinnamon Fruit Puree		
	Name of the company that makes (or compounds) the product	Wanabana LLC		
	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 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	Oral	If Other	
	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		

Date the person reduced dose of the product	28-Oct-2023	
Give best estimate of duration		
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)	4.5 Year(s)
Date of Birth	
Weight	17.55 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 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	
City	
State/Province	(b)(6)
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	(b)(6)

	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)?	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	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-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

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	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 ☐ 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)

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 1 of 1

Test Name	LEAD	Test Date	31-Oct-2023

	Test Result	4	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0	High Test Range		
	More Information Available?				

Additional Comments

Section 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

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 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 ☐ 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 the product again?	Doesn't Apply			

Drug 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		
	How was it taken or used	Oral	If Other		

Date the person first started taking or using the product	20-Oct-2023	
Date the person stopped taking or using the product	24-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 product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)		
Date of Birth	(b)(6)	
Weight	12.6 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.

Probiotic, Vitamin C, Childrens multivitamin

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)

	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	

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	☑ 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

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	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 ☐ 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)

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 1 of 1

Test Name	LEAD	Test Date	31-Oct-2023

	Test Result	5	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0	High Test Range		
	More Information Available?				

Additional Comments

Section 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

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 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 ☐ 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 the product again?	Doesn't Apply			

Drug 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		
	How was it taken or used	Oral	If Other		

	Date the person first started taking or using the product	20-Oct-2023
	Date the person stopped taking or using the product	24-Oct-2023
	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)

	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	

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-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

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)	☐ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☑ Other Serious or Important Medical Events ☐ Disability or Permanent Damage

		☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
	Date of Death	
	Date of Event	10-Nov-2023
	Date of this Report	17-Nov-2023

Describe Event, Problem or Product Use Error

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.

Relevant Test/Laboratory Data 1 of 1

	Test Name	LEAD BLOOD (PEDIATRIC) VENOUS	Test Date	10-Nov-2023
	Test Result	6.4	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range	0.0	High Test Range	3.4
	More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

	Product Available for Evaluation? (Do not send product to FDA)	Yes
	Returned to Manufacturer on	
	Do you have a picture of the product? (check yes if you are including a picture)	Yes

D. PRODUCT(S) 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	Drug/Biologic
	This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	Wana Bana Apple Cinnamon Fruit Puree Pouches		
	Strength		If Other	
	Manufacturer/Compounder	Wana Bana-Austrofood		

	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	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 given when patient wanted it.

E. SUSPECT MEDICAL DEVICE

	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	

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

Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b)(6)		
Middle Name			
First Name	(b)(6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b)(6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Other Health Professional	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	No		

Manufactured by: AUSTROFOOD
S.A.S. Av. Gral. Enriquez Y
Nicaragua (Esq.), Quito Ecuador.
Imported in USA by: Wanabana
Wanabana USA, LLC 2113 W.
Street - Jacksonville FL 32209.
888-272-7184
0032-BPM-AN-0818
N 2337.

Store in cool dry place. Once opened refrigerate and consume within 5 days.

WARNING: This package has a small cap. This product's cap should be opened under adult supervision.

- BPA Free Packaging
- Gluten Free
- Ready to eat

For more products visit:

7 862118 149278

Nutrition Facts

1 Serving per package
Serving Size: 1 pouch (71g)

Amount per serving
Calories 50

	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 2g	7%
Total Sugars 9g	
Includes 0g Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

EXP 03-2[illegible]-2024
LOT [illegible]102[illegible] 23 16:59

	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		
	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 sauce pouches		
	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			
	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		

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-Sep-2022		
	Date the person stopped taking or using the product	06-Nov-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 product? (such as what condition was it supposed to treat) 1 of 1

	To eat

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who 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	
	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)

Lead poisoning

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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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)?	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	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

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	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)	

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)

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.

Relevant Test/Laboratory Data 1 of 1

Test Name	SERUM LEAD	Test Date	31-Oct-2023
Test Result	20.4 mcg/dL	Test Unit	UNKNOWN

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Apple Cinnamon Fruit Purée			
	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				
	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	26-Jun-2024			
	Lot number	04023:26			
	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	1 Month	
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Baby food

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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	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

	☐ Asian ☑ White ☐ Black or African American

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

None prior to discovery of high lead levels

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.)

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.

Poly Vi Sol multivitamin

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	07-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	


Nutrition Facts
1 Serving per package
Serving Size: 1 pouch (71g)
Amount per serving
Calories 50
% Daily Value*
Total Fat 0g 0%
Saturated Fat 0g 0%
Trans Fat 0g
Cholesterol 0mg 0%
Sodium 0mg 0%
Total Carbohydrate 12g 4%
Dietary Fiber 2g 7%
Total Sugars 9g
Includes 0g Added Sugars 0%
Protein 0g
Vitamin D 0mcg 0%
Calcium 4mg 0%
Iron 0.2mg 0%
Potassium 60mg 0%
* The % Daily Value (DV) tells you how much a nutrient in a 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: 04023:26
EXP:06-26-2024
KOSHER
WANA BANA
Net Weight: 7.50 oz (213 g)
APPLE
CINNAMON
FRUIT PUREE
•No preservatives
•Gluten free
3 PACK


Manufactured by: AUSTROFOOD S.A.S. Av. Gral. Enriquez y Tanicuchi (Esq.), Quito Ecuador.
Imported in USA by: Wanabana USA, LLC 2113 W. 30 Street - Jacksonville FL 32209.
Phone: 888-272-7784
UPC CODE: 00132-BPM-AN-0818
Nutrition Facts
1 Serving per package
Serving Size: 1 pouch (71g)
Amount per serving
Calories 50
% Daily Value*
Total Fat 0g 0%
Saturated Fat 0g 0%
Trans Fat 0g
Cholesterol 0mg 0%
Sodium 0mg 0%
Total Carbohydrate 12g 4%
Dietary Fiber 2g 7%
Total Sugars 9g
Includes 0g Added Sugars 0%
Protein 0g
Vitamin D 0mcg 0%
Calcium 4mg 0%
Iron 0.2mg 0%
Potassium 60mg 0%
* The % Daily Value (DV) tells you how much a nutrient in a 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
7 862118 149278
EXP: 06-26-2024
LOT: 04823:26 16:32
WANA BANA
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz (71g)

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	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

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	[redacted]
	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 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

		☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
	Date of Death	
	Date of Event	01-Nov-2023
	Date of this Report	08-Nov-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient ingested 3-4 pouches of Wana Bana apple fruit puree. He tested for an elevated blood lead level of 8.1

Relevant Test/Laboratory Data 1 of 1

	Test Name	VENOUS BLOOD LEAD	Test Date	01-Nov-2023
	Test Result	8.1	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range	<3.4	High Test Range	
	More Information Available?			

Additional Comments

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	
	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
	Type	Drug/Biologic
	This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	Wana Bana		
	Strength		If Other	
	Manufacturer/Compounder			

	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			

Drug 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?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	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		

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	(b)(6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b)(6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Physician	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	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	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

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	07-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)		

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 toddler had a wanabana apple sauce pouch. The folllw day it hit national news that they were recalled. I took him in to get a lead test & his tests came back high.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD TEST	Test Date	07-Nov-2023	
Test Result	6.1	Test Unit	MILLIGRAMS PER DECILITRE	

	Low Test Range		High Test Range		
	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)	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 appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Mango & Banana			
	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				
	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		
	Give best estimate of duration		
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 ☐ 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	08-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	

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	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-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

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)	

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 daughter consumed Wana Bana pouches from February 2023 until the date of the recall. Her bloodwork indicates a lead level of 7.4. Her bloodwork levels were normal at her one year check up. The only thing that has changed about her diet or environment is giving her the pouches.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD VENOUS	Test Date	03-Nov-2023	
Test Result	7.4	Test Unit	MICROGRAMS PER DECILITRE	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Section 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

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 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 ☐ 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 the product again?				

Drug 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 taking or using the product	26-Feb-2023			

	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?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Nutrition, not for medical condition treatment

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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

☐	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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	10-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	

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	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

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

A. PATIENT INFORMATION

	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 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

		☐ 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

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Ingestion of WanaBana cinnamon applesauce. Was given a box for Halloween and had several prior to family hearing about recall. Had appointment in clinic on 11-9-23. Lab draw for lead level. Was elevated at 6.7 (reference < 3.4)

Relevant Test/Laboratory Data

1 of 1

	Test Name	LEAD, BLOOD	Test Date	09-Nov-2023
	Test Result	6.7	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range		High Test Range	3.4
	More Information Available?			

Additional Comments

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	
	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
	Type	Drug/Biologic
	This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

	Product Name	WanaBana Cinnamon Applesauce		
	Strength		If Other	
	Manufacturer/Compounder			

	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

E. SUSPECT MEDICAL DEVICE

	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	

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	(b)(6)		
Address			
City			
State/Province/Region			
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b)(6)		
Phone			
Email			
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Nurse Practitioner	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer	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	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

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 ☐ 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)

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.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD, BLOOD	Test Date	16-Jun-2023	
Test Result	8.6	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		

	More Information Available?				

Relevant Test/Laboratory Data 2 of 2

	Test Name	LEAD, BLOOD	Test Date	28-Sep-2023	
	Test Result	1.9	Test Unit	MICROGRAMS PER LITRE	
	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Lead level went down after having my child refrain from eating these fruit pouches (about a month and a half later).

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		
	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 fruit pouches		
	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			
	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-Aug-2022			
	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				
	Is therapy still on-going?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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	

	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	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	

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-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

	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-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 ☐ 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)

My son was lead poisoned with a BLL of 13. His consumption of the cinnamon apple pouches made by WanaBana coincide 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.

Relevant Test/Laboratory Data 1 of 1

	Test Name	VENOUS LEAD TEST	Test Date	22-Mar-2023	
	Test Result	13	Test Unit	MICROGRAMS PER MIL LILITRE	

	Low Test Range	0	High Test Range	Indefinite	
	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			
	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)	apple cinnamon fruit puree			
	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?	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				

	Date the person stopped taking or using the product		
	Date the person reduced dose of the product		
	Give best estimate of duration	2 Month	
	Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 ☐ 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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):	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	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

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	06-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)

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)

On 10/06 we took our daughter in for her 12 month well visit and later got the call that her lead was elevated to 4.2 prior to the recall we were going through all the avenues of what may have caused it to happen. After the recall we found out that those are the pouches she was having at her grandparents house. They have all been tossed now and hoping by her 15 month visit her level will be down

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD (VENOUS)	Test Date	06-Oct-2023
Test Result	4.2	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	3.5
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		
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 apple cinnamon fruit puree pouches		
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?			
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			
Date the person stopped taking or using the product			
Date the person reduced dose of the product			

Give best estimate of duration	4 Month	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section 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	9.045 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 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		
City		
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number		
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):	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	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-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

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	09-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)	

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 son was eatting WanaBana apple/cinnamon packets, his lead levels were 13 on a lead test.

Relevant 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	

	More Information Available?	

Additional Comments

Pediatrician notified my wife and I of the results.

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		
	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 Apple Cinnamon		
	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?			
	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	28-May-2023		
	Date the person stopped taking or using the product	04-Nov-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 product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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)

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 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	(b)(6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	14-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	

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	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		

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	25-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)

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 son who is now 3 as of (b)(6) lab results came back with high level of lead in his blood

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD BLOOD, CAPILLARY	Test Date	31-Oct-2023
Test Result	12.8	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	3.5	High Test Range	5.0

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	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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 ☐ 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 son used to eat the Wana Bana fruit pouches, which came out today as being recalled for lead. After his 2 year well visit, 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.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD, BLOOD	Test Date	16-Jun-2023
Test Result	8.6	Test Unit	MICROGRAMS PER MILLILITRE
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	LEAD, BLOOD	Test Date	28-Sep-2023	
Test Result	1.9	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

This was after we stopped giving him the Wana Bana fruit 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		
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 fruit pouches		
Name of the company that 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?	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-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 product? (such as what condition was it supposed to treat) 1 of 1

	Toddler snack

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 age)	2 Year(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)
Number/Street	
City	
State/Province	

	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number		
	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)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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	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	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)	

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 son ingested lead contaminated apple sauce.

Relevant Test/Laboratory Data 1 of 1

	Test Name	PEDS LEAD	Test Date	30-Oct-2023
	Test Result	6.7	Test Unit	MICROGRAMS PER DECILITRE

Low Test Range	0	High Test Range	3.5	
More Information Available?				

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Wana bana		
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			
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	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	
Date the person first started taking or using the product	01-Jul-2023		

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 product? (such as what condition was it supposed to treat) 1 of 1

Food

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 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.

Cefdinir

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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


KOSHER
WANA BANA
Net Weight:
7.50 oz
(213 g)
APPLE
CINNAMON
FRUIT PUREE
•No preservatives
•Gluten free
3
PACK

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>

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

Relevant Details

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

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>
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>
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	oz
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

Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	2.5
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	Not Applicable
Did the event reoccur when product use resumed?	Not Applicable
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

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

Ingredient Details

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

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.04
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 4 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011555
Select identifier type	Other
If other, please describe	Pack x4 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 estimate duration of use below. Start:	<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>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<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	oz
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>
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>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<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	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 estimate duration of use below. Start:	<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>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<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	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	oz
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>
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>

Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<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 Relevant Details

I have reviewed the ingredients listed for	

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

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	oz
Barcode identifier	782118149278
Select identifier type	Other
If other, please describe	Pack x 3 units
Diagnosis or reason for use (indication):	<blank>
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>

Concomitant Ingredient Details

Ingredient name	Apple puree

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	oz
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

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<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>

Concomitant Ingredient Details

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	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
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	oz
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>
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>

Concomitant Ingredient Details

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	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 12 units

Product manufacturer, packer, distributor or other responsible party	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

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<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>

Concomitant Ingredient Details

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	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	oz
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

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<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

Concomitant Ingredient Details

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	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 Relevant Details

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

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		
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

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)

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 son has a lead level of 28.8 micrograms per deciliter after eating WanaBana puree packs. We're in (b)(6) He's getting a venous blood test tomorrow to confirm the level.

Relevant Test/Laboratory Data 1 of 1

Test Name	BLOOD TEST (CAPILLARY)	Test Date	01-Nov-2023
Test Result	28.8	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	3.4

	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		
	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		
	Name of the company that 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?	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		If Other	
	Frequency		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		
Give best estimate of duration	6 Month	
Is therapy still on-going?	Yes	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)	1 Year(s)
Date of Birth	
Weight	10.35 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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	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	

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-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

	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)

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)

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.

Relevant Test/Laboratory Data 1 of 1

	Test Name	LEAD (VENOUS)	Test Date	30-Oct-2023
	Test Result	15.5	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Apple cinnamon fruit puree		
	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	31-Mar-2024		
	Lot number	01023311205		
	Dosage Form			
	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		

Date the person reduced dose of the product	30-Oct-2023	
Give best estimate of duration		
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

To eat

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section 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	10.35 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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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):	No	


WANA BANA
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
NO SUGAR ADDED
Net Weight: 2.50 oz

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	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)	

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)

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)

We were made aware of a recall for Wanabana fruit pouches as they contained high levels of lead. Our daughter consumed these pouches so we called our pediatric office and they recommended that our daughter get a blood draw to check her lead levels. We had her tested and received the news that she had high levels of lead, though not high enough that it needed immediate medical attention. We were advised to check her blood again in 6 months.

Relevant Test/Laboratory Data 1 of 1

	Test Name	BLOOD TEST FOR LEAD	Test Date	31-Oct-2023
	Test Result	5	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range	0	High Test Range	3.5
	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		
Type	Drug/Biologic		
This report is about			
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	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			
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		If Other	
Frequency	As needed	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	01-Jul-2022		
Date the person stopped taking or using the product	01-Nov-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 product? (such as what condition was it supposed to treat)	1 of 1
Food	

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section 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	9 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.
Vitamin D

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	(b)(6)
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):	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	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	06-Jun-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)

My child tested positive for high levels of lead in his blood after having a baseline of no lead 6 months prior. We had our house, his daycare, and family members houses tested including the soil and water with no answer. He eats "wanna banana" pouches regularly. With the new recall we believe that is how he obtained lead posioning.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD	Test Date	06-Jun-2023
Test Result	11	Test Unit	
Low Test Range	0	High Test Range	

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	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	22-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)	

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 son ate Apple Cinnamon WanaBana fruit puree pouches as a regular part of his diet (4-6 pouches a day) from May 2023 through August 2023. He had his blood lead levels tested on 8/22/2023 as part of a routine screening for daycare and they came back as 19.8ug/dL. The pediatrician, (b)(6) Health department were working to identify the source of exposure, but home studies, dust wipes, and the XRF gun did not detect a source of exposure for my son in our home. Additionally, my husband and I hired an independent company to perform a separate study that yielded no source of lead exposure in the home. Daycare was also deemed to be an unlikely source of exposure as none of the other children at my son's licensed daycare had elevated lead levels on their tests. Since my son's diagnosis, we have been following the EPA's lead poisoning healthy diet, and in doing so, have eliminated the WanaBana apple cinnamon fruit puree pouches from his diet. His blood lead levels test was repeated on 9/1/2023, 9/14/2023, 9/26/2023, and 10/25/2023. The results were 22.5ug/dL, 22.4ug/dL, 14.3ug/dL, and 9.6ug/dL respectively. My son is currently in treatment at (b)(6) for lead poisoning and is enrolled in the local (b)(6) as a result of this lead exposure. His levels are trending down, but we are extremely concerned about future developmental delays and behavioral issues resulting from this exposure.

Relevant Test/Laboratory Data				1 of 5
Test Name	LEAD LEVEL, BLOOD (PEDIATRIC)	Test Date	22-Aug-2023	
Test Result	19.8	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range	0	High Test Range	3.4	
More Information Available?				

Relevant Test/Laboratory Data				2 of 5
Test Name	LEAD LEVEL, BLOOD (PEDIATRIC)	Test Date	01-Sep-2023	
Test Result	22.5	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range	0	High Test Range	3.4	
More Information Available?				

Relevant Test/Laboratory Data				3 of 5
Test Name	LEAD LEVEL, BLOOD (PEDIATRIC)	Test Date	14-Sep-2023	
Test Result	22.4	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range	0	High Test Range	3.4	
More Information Available?				

Relevant Test/Laboratory Data				4 of 5
Test Name	LEAD LEVEL, BLOOD (PEDIATRIC)	Test Date	26-Sep-2023	
Test Result	14.3	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range	0	High Test Range	3.4	
More Information Available?				

Relevant Test/Laboratory Data				5 of 5
Test Name	LEAD LEVEL, BLOOD (PEDIATRIC)	Test Date	25-Oct-2023	
Test Result	9.6	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range	0	High Test Range	3.4	
More Information Available?				

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	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 ☐ 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?	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	31-Dec-2023		
	Lot number	10022:31 08:10		
	Dosage Form			
	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		
	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 product? (such as what condition was it supposed to treat) 1 of 1

It was marketed as food for babies and toddlers to eat.

	Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)	
Date of Birth	(b)(6)
Weight	11.61 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)

Elevated Blood Lead Level

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.

Poly-Vi-Sol

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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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)?	No
If you do NOT want your identity disclosed to the	No

manufacturer, please mark this box (Confidentiality Requested):		


WANA BANA
No preservatives
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight:

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	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	09-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)

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 1 of 1

	Test Name	IRON	Test Date	09-Oct-2023
	Test Result	Low (don't remember exact number)	Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

PCP is (b)(6)

Section 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

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 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 ☐ 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?	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	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		

	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	[redacted]
	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 ☐ 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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


WAKA BANA
No preservatives
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz (71g)

Manufactured by: [illegible]
S.A.S. Av. [illegible]
Tani[illegible] Warnatbana
Imported in USA BY: Warnatbana USA, LLC 2113 W.
LLC - Jacksonville FL 32209.
30[illegible]-272-7184
Phone: 0032-BPM-AN-0818
GMP [illegible] 2337.
Wort[illegible] dry place. Once
[illegible]perate and
[illegible]in 5 days.
Cons[illegible]is package has a
WAI[illegible]his product's cap
[illegible]pened under adult
shal[illegible]
sup[illegible]

Packaging

- Bl[illegible]
- G[illegible]
- P[illegible]

[illegible] products visit:

Nutrition Facts

[illegible] per package

[illegible] Size: 1 pouch (71 g)

Amount per serving	
Calories	**50**
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 2g	7%
Total Sugars 9g	
Includes 0g Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

7 862118 149278

EXP : 09-21-2024
LOT : 07023 : 21 15 : 42

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-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

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	20-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 ☐ 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)

Our daughter born on 5/14/2022 had a regular primary care appointment on 6/1/2023 and had the scheduled lead test through finger prick that came back as a 14 lead count, after they found those numbers we were asked to get a blood draw to get a more accurate number that will be shown below in relevant tests. The blood drawn test came back with still raised lead levels and we had the (b)(6) Health Department come out to do a check and they couldn't find anything that they didn't think raised concerns for lead. After that meeting with the health department they asked us to do another blood draw 3 months later that came back higher than the first blood draw, so she was still being exposed with no answers. After trying to get the health department to come back out to do another check, they didn't think it was necessary to check our homes, toys, or any of her food. After a month of trying to get the health department to come back out, the FDA released that the Wanabana Purée pouches had been recalled due to high lead content and our daughter had been consuming those over the last 9 months averaging 4-6 a week.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD BLOOD TEST	Test Date	20-Jun-2023
Test Result	7.1 mcg/dL	Test Unit	

Low Test Range	< 3.5	High Test Range		
More Information Available?				

Relevant Test/Laboratory Data 2 of 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?			

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Wanabana purée pouch		
Name of the company that 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 the product again?			

Drug Therapy 1 of 1

Expiration date	
Lot number	

	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				
	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?				

Why was the person using the product? (such as what condition was it supposed to treat)	1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

Section 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	11.7 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.

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	

	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	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	


WANA BANA
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz (71g)

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

	Patient Identifier (In Confidence)	[redacted]
	Age	17 Month(s)
	Date of Birth	
	Sex	Female
	Gender	Decline to answer
	Please Specify Other Gender	
	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
	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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	01-Nov-2023
Date of this Report	03-Nov-2023

Describe Event, Problem or Product Use Error

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

Relevant Test/Laboratory Data

1 of 1

Test Name	LEAD VENOUS	Test Date	01-Nov-2023
Test Result	10.8	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

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	
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
Type	Drug/Biologic
This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	WanaBana fruit pouch		
Strength		If Other	
Manufacturer/Compounder			

	NDC# or Unique ID	
	Product Type(check all that apply)	☑ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
	Event Abated After Use Stopped or Dose Reduced?	Yes
	Event Reappeared after Reintroduction ?	Doesn't Apply

Drug 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?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	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	

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

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

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-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

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	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)

I made a 1st time purchase of WanaBana cinnamon applesauce from Dollar Tree for my 1 year old. The next day 10/25/23 his babysitter reported to me that he didn't have much of an appetite all day. The following morning 10/26/23 my son woke up an 5am vomiting. I called my sons pediatrician to make an appointment. They advised me to watch my son closely over the weekend for signs of dehydration, if no improvement by Monday they would see him in clinic. He had vomiting and diarrhea over the weekend. He was seen at her pediatricians office Monday Oct 30 where he was diagnosed with the stomach flu. When I returned home I laid my son down for a nap. After doing so I got online and saw a news article about an Urget recall for WanaBana apple cinnamon pouches. Immediately I called his doctor back to report my concern. I left a message with the front office and waited for a response. In the meantime I took my son to the lab at the hospital to have bloodwork done for his lead 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.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD LEVEL BLOODWORK	Test Date	30-Oct-2023

	Test Result	4.2	Test Unit	GRAMS PER LITRE	
	Low Test Range		High Test Range		
	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)	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 appears on the box, bottle, or package (Include as many names as you see)	WanaBana Cinnamon applesauce pouch			
	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?				
	Did the problem return if the person started taking or using the product again?				

Drug Therapy 1 of 1

	Expiration date	25-Jun-2024			
	Lot number	04023 25			
	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	24-Oct-2023	
Date the person stopped taking or using the product	24-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 product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On		

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)		
Date of Birth	(b)(6)	
Weight	9.9 kg	
Ethnicity (Choose only one)	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)

NKDA

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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)

	Telephone number	(b)(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	


WAKA BANA®
No preservatives
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz (71g)

urfactured by: AUSTROFOOD
S. Av. Gral. Enriquez y
Iaucho Casa 3, Quito Ecuador.
ported in USA by: Wanabana
Wanabana USA, LLC 2115 W.
street - Jacksonville FL 32209.
one: 888-272-7184
P CODE: 0032-BPM-AN-0818
orma INEN 2337-

store in cool dry place. Once
opened, refrigerate and
consume within 5 days.

WARNING: This package has a small cap. This product's cap should be opened under adult supervision.

- **BPA Free Packaging**
- **Gluten Free**
- **Ready to eat**

For more products visit:

Nutrition Facts

1 Serving per package
Serving Size: 1 pouch (71g)

Amount per serving	
Calories	50
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 2g	7%
Total Sugars 9g	
Includes 0g Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

EXP: 06-25-2024
LOT: 04023:25 22:50

862118 +9278

CTU Trace Data: 06-N

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	02-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)	

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 daughter was a consumer of WanaBana Apple-Cinnamon fruit pouches over the past year, upon seeing the recall notice I got her bloodwork tested last week and immediately threw out all pouches. Her lead level was 16.9, and the [redacted] DOH is aware as well. https://www.fda.gov/food/outbreaks-foodborne-illne ss/investigation-elevated-lead-levels-applesauce-p ouches-november-2023

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD	Test Date	02-Nov-2023
Test Result	16.9	Test Unit	
Low Test Range		High Test Range	

	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		
	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 Apple Cinnamon Fruit Puree pouch		
	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?			
	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	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		
Give best estimate of duration		
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Snack

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	[redacted]
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
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.

Has now started iron supplements to increase speed in which lead will leave the body

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	
City	
State/Province	--
Country	UNITED STATES
ZIP or Postal code	
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)?	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	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 well-child 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 (b)(6). It's possible that the packets were purchased at a (b)(6) Dollar Tree.

Relevant Test/Laboratory Data 1 of 2

Test Name	BLOOD-STICK TO CHECK 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?				

Relevant Test/Laboratory Data 2 of 2

Test Name	VENOUS BLOOD-DRAW TO CHECK FOR LEAD LEVELS	Test Date	12-Oct-2023
Test Result	4.3	Test Unit	
Low Test Range	0	High Test Range	3.5
More Information Available?			

Additional Comments

Section 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

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 appears on the box, bottle, or package (Include as many names as you see)	Wanna Banana		
Name of the company that makes (or compounds) the product	Austrofood		
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 the product again?		

Drug Therapy 1 of 1

Expiration date	18-Apr-2024			
Lot number	Unable to read			
Dosage Form				
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				
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 product? (such as what condition was it supposed to treat) 1 of 1

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

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 age)	
Date of Birth	(b)(6)
Weight	11.25 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)

Global Development Delays, Suspected Early Autism

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

Amoxicillin

List any other important information 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.

List all current prescription medications and medical devices being used.

Albuterol nebulizer, Triamcinolone- both PRN

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

Pediasure

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		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	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)?	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	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	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)

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)

Child consumed Wananbana Apple Cinnamon pouch and was blood tested. Child has high level of lead on blood work

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD, BLOOD (PEDS) VENOUS	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 shows high level of lead.

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		
	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 Apple Cinnamon pouch		
	Name of the company that 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?	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		
	Date the person stopped taking or using the product	27-Oct-2023		

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 product? (such as what condition was it supposed to treat) 1 of 1

It was a snack

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	[redacted]
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)	☐ 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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
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	

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)

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	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)	

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)

WanaBana fruit pouches were a consistent part of our babies diet. During a routine exam he was found to have lead poisoning. We live in a new construction home and a home inspection was performed by the county on August 23, 2023. No sources of lead that our baby (b)(6) had access to were found. Our other young child who did NOT eat this product was tested for lead and found to be normal. We immediately stopped purchasing this product after we received the July results of (b)(6) bloodwork. We feel certain his high lead levels were a result of this dangerous product.

Relevant Test/Laboratory Data 1 of 3

Test Name	ROUTINE LEAD TEST	Test Date	05-Jul-2023
Test Result	12.9	Test Unit	MICROGRAMS PER DECILITRE

Low Test Range	0	High Test Range	5	
More Information Available?				

Relevant Test/Laboratory Data 2 of 3

Test Name	VENOUS BLOOD DRAW LEAD TEST	Test Date	02-Aug-2023
Test Result	13.1	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	5
More Information Available?			

Relevant Test/Laboratory Data 3 of 3

Test Name	VENOUS BLOOD DRAW LEAD TEST	Test Date	05-Oct-2023
Test Result	8.8	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range	0	High Test Range	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		
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 Apple cinnamon fruit puree		
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?	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-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?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Returned to Manufacturer On	

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 ☐ 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	07-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

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	☑ 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

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	07-Nov-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)

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 ouches-november-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.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD BLOOD TEST	Test Date	07-Nov-2023
Test Result	4.8	Test Unit	MICROGRAMS PER DEC ILITRE
Low Test Range	<3.5	High Test Range	>3.5

	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		
	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 apple cinnamon		
	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?			
	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		
Give best estimate of duration	3 Month	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Food

Returned to Manufacturer On	

Section D - About the Medical Device

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 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 out (If relevant)	

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 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 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)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	07-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	

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

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	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)

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 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

Relevant Test/Laboratory Data 1 of 1

Test Name	BLOOD LEAD TEST, VENOUS	Test Date	31-Oct-2023
Test Result	13	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section 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

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 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 ☐ 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 the product again?	Doesn't Apply		

Drug 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		
	Date the person stopped taking or using the product	28-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 product? (such as what condition was it supposed to treat) 1 of 1

	Food

	Returned to Manufacturer On		

Section D - About the Medical Device

	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 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 out (If relevant)	

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 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 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.)

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 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	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	08-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	

ufactured by: AUSTROFOOD
. Av. Gral. Enríquez y
uchí (Esq.), Quito Ecuador.
rted in USA by: Wanabana
Vanabana USA, LLC 2113 W.
eet - Jacksonville FL 32209.
e: 888-272-7184
CODE: 0032-BPM-AN-0818
ma **INEN 2337.**

e in cool dry place. Once
ened, refrigerate and
sume within 5 days.

NING: This package has a
sn cap. This product's cap
sh be opened under adult
supervision.

- Free **Packaging**
- Free
- ady **to eat**

For more **products visit:**

7 862118 149278

Nutrition Facts

1 Serving per package
Serving Size: 1 pouch (71g)

Amount per serving	
Calories	**50**
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 12g	4%
Dietary Fiber 2g	7%
Total Sugars 9g	
Includes 0g Added Sugars	0%
Protein 0g	
Vitamin D 0mcg	0%
Calcium 4mg	0%
Iron 0.2mg	0%
Potassium 60mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a 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

EXP: 12- 2023
LOT: 100- 21 - 12 - 19


WAKA BANA
preservatives
Gluten free
APPLE
CINNAMON
FRUIT PUREE
"I AM FRUIT"
KOSHER
NO SUGAR ADDED
Net Weight: 2.50 oz (71g)