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

es: 6

	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	Yes			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Apple cinnamon fruit puree			
	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 of Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug 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	07-Nov-2023			

Generated by: SYSTEM Generated on: 15-Nov-2023 14:20:24 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-84264 | Department: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pages: 6

	Date the person reduced dose of the product								
	Give best estimate of duration								
	Is therapy still on-going?			-					
WI	ny was the person using the pr	oduct? (such as what	con	dition was it supposed to tre	eat)		1 of 1	
	Favorite apple sauce								
	Returned to Manufacturer On								
Se	ection D - About the Medical De	evice							
	Name of medical device								
	Name of the company that makes the medical device								
Ot loc	her identifying information (The cate them)	e model,	catalog, lot, s	seria	ll, or UDI number, and the ex	xpirat	ion date, if	you can	
	Model Number								
	Catalog Number								
	Lot Number								
	Serial Number								
	UDDI Number								
	Expiration date								
	Was someone operating the medical device when the problem occurred?								
Fo	r implanted medical devices O	NLY (su	ch as pacema	aker	s, breast implants, etc.)				
Da	ate the implant was put in				Date the implant was taken out relevant)	(If			
Se	ection E - About the Person Wh	o Had t	ne Problem_						
	Person's Initials	(b)(6)							
	Sex	Male							
	Gender	Cisgeno	ler man/boy						
	Please Specify Other Gender								
	Age (specify unit of time for age)								
	Date of Birth	(b)(6)							
	Weight	16.65 kg	9						
	Ethnicity (Choose only one)	Not His	panic/Latino						
	Race (Check all that apply)		can Indian or Alaska						

Generated by: SYSTEM Generated on: 15-Nov-2023 14:20:24 Page 3 of 5

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

es: 6

	White Black or African American	
Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	N/A	
PΙε	ease list all allergies (such as to drugs, foods, pollen or others)	
	N/A	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medications and medical devices being used.	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
	Cilantro heavy metal detox	
IS 0	ection 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 Number/Street (b)(6)	
	Number/Street City	
	State/Province	-
	Country UNITED STATES	
	ZIP or Postal code	
	ZIP or Postal code Telephone number Email address	
	Email address	

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

es: 6

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	

Generated by: SYSTEM Generated on: 15-Nov-2023 14:20:24 Page 5 of 5



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

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

Basic Det	ails	WIT-03.00) time zone		
Company		CDER-CTU	Originating Account	FAERS
Source Me		MWO (Drug)	Source Form Type	E2B XML 3500B
Priority		Routine		
-	Auto Calculation Rule	No		
FDA Rece		15-Nov-2023	CTU Received Date	15-Nov-2023
CTU Triag			CTU Data Entry Date	
Report Ty		Spontaneous	Report Classification	Drug
Assign To	•	User		
User/Grou				
	Department	Moder (cder oce r	SS-CTU@fda.hhs.gov) (E2B)	
Case Prior		Direct	SS-CTO@fda.nns.gov) (E2B)	
		5.1000		
Contact				
Case	First Name	Last Name	Email Address	Phone
Reporter		Edot Name		
\checkmark	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A	- About the Problem			
Date the Serious Did any (Check A.Tell us wany addition My sor headage	y of the following happen? a all that apply) what happened and how onal documents if neces has consumed some appleches. We checked packaging	Used a product incorrectly when Noticed a problem with the quality Had problems after switching 29-Oct-2023 No Hospitalization - admitted or substitution of the Notice	from one product maker to another maker	ce been complaining of atched the names and batch
Relevant	Test/Laboratory Data			1 of 1
Test N	ame	LEAD PANEL	Test Date	09-Nov-2023
Test R	esult	Positive for lead	Test Unit	
1	1.5		15.1 T 15	

Low Test Range	High Test Range		
More Information Available?			

Generated by: SYSTEM Generated on: 15-Nov-2023 20:15:40 Page 1 of 5

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

es: 7

Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	Yes			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic	-		
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cinnamon 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 of Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?				
Dr	ug 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				

Generated by: SYSTEM Generated on: 15-Nov-2023 20:15:40 Page 2 of 5

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

	Give best estimate of duration		
	Is therapy still on-going?		
Wŀ	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Otl	her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh		
	Person's Initials	(b)(6)	_
	Sex	Male Cia read on rear //s and	
	Gender Places Specify Other Conder	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)		-
	rade (Oneok ali tilat apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	

Generated by: SYSTEM Generated on: 15-Nov-2023 20:15:40 Page 3 of 5

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

Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	Autism Spectrum, ADHD, sensory processing disorder	
PI	ease list all allergies (such as to drugs, foods, pollen or others)	
	Unknown	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
LIS	st all current prescription medications and medical devices being used.	
	Adderall, Vyvanse, Abilify and Guanfacine	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
اج	ection F - About the Person Filling Out This Form 1 of 1	
00	Primary? Yes	
		-
	Reporter is Patient?	
	Title	Ш
	Last name (b)(6)	
	Middle Name	
	First name / L / C /	
	Number/Street	
	Number/Street (b)(6)	
	State/Province	
	Country UNITED STATES	
	ZIP or Postal code Telephone number Email address (b)(6)	+
	Email address	-
	Fax	\vdash
	Reporter Organization	\vdash

Generated by: SYSTEM Generated on: 15-Nov-2023 20:15:40 Page 4 of 5

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

es: 7

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

Generated by: SYSTEM Generated on: 15-Nov-2023 20:15:40 Page 5 of 5

WANA BANA Net Weight: 7.50 oz (213 g)

APPLE GENERALISMON FRUIT PUREE

- No preservatives
- Gluten free

(S) PACK

al Fat Og	4400000 CTUTTO DATE OF NEW 2002 Tabel
CTU No.: FDA-CDER-5TV-2V25-64316 Department: CFSAN RCT No.: RCT-	+180289 CTO Triage Date: 15-Nov-2023 Total
esterol Omg	0%
esteror	0%
ım 0mg Carbohydrate 12g	4%
ary Fiber 29	7%
Sugars 9g Sludes 0g Added Sugars	0%
n Og	0%
D Omeg	0%
1 4mg	0%
mg ım 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

CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag

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-R	RSS-CTU@fda.hhs.gov) (E2B)					
Case Priority	Direct	<u></u>					
Contact							
Case First Name	Last Name	Email Address	Phone				
Reporter (b)(6)	(b)(6)	(b)(6)	(h)(6)				
		(6)(6)					
Section A - About the Problem							
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side e	effect (including new or worsening symptoms))				
(Crieck all that apply)	Used a product incorrectly wh	nich could have or led to a problem					
	Noticed a problem with the quality of the product						
	-	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						
(Official and apply)	Required help to prevent permanent harm						
	Disability or health problem						
	Birth defect						
	Life-threatening						
	Death						
Other perious/important medical	Other serious/important medic	cal incident(Please Describe Below)					
Other serious/important medical incident(Please Describe Below)							
4.Tell us what happened and ho any additional documents if nec	4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for						
My daughter received a blood test with results of abnormal levels of lead in her blood. She has been more irritable and crank			een more irritable and cranky				
ing adagned received a blood tes	or man results of abhormal lev	olo ol lodd ill flor blood. Ollo flas be	20.1 more irritable and oranity.				

R	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		

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:26 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag

es: 5

	More Information Available?				
Ac	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana bana apple cinnamon f	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 a Generic Biosimilar	an Outsourcing Facility		
	Strength		If Other		
	NDC number	-			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	rug 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	15-Feb-2023			

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag

	Date the person reduced dose of the product					
	Give best estimate of duration					_
	Is therapy still on-going?		_			
W	ny was the person using the pr	od	uct? (such as what cond	dition was it supposed to treat)	1 of 1	
	Good pick pouch					
	Detumed to Manufacturer On					_
	Returned to Manufacturer On					
Se	ction D - About the Medical De	evi	е			
	Name of medical device					
	Name of the company that makes the medical device					
Ot	her identifying information (The	e n	odel, catalog, lot, serial	, or UDI number, and the expiration dat	te, if you can	
loc	cate them)					
						_
	Model Number		_			
	Catalog Number					
	Lot Number					
	Serial Number					
	UDDI Number					
	Expiration date					
	Was someone operating the					
	medical device when the problem occurred?					
Fo	r implanted medical devices C	NI	Y (such as pacemakers	s breast implants etc.)	<u> </u>	
	ate the implant was put in		•	Date the implant was taken out (If		
				relevant)		
Se	ction E - About the Person Wh	10	Had the Problem			
	Person's Initials	(b)(6)			
	Sex	F	emale			
	Gender	С	sgender woman/girl			
	Please Specify Other Gender					_
	Age (specify unit of time for age)					_
	Date of Birth	(b)(6)			
	Weight).8 kg			_
	Ethnicity (Choose only one)	N	ot Hispanic/Latino			_
	Race (Check all that apply)	Г	American Indian or Alaska Native	2		_
			Native Hawaiian or Other Pacific			
			Asian	-		

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag

es: 5

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 Number/Street City State/Province			White Black or African American	
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 Number/Street City	Lis	st known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, 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 Number/Street City				
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 Number/Street City	PΙ	ease list all allergies (such as t	to drugs, foods, pollen or others)	
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 Number/Street City				
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 Number/Street City	Lis	st any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
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 Number/Street City				
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 Number/Street City	Lis	st all current prescription medic	cations and medical devices 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 Number/Street City				
Primary? Yes Reporter is Patient? Title Last name (b)(6) Middle Name First name Number/Street City	Lis	st all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Primary? Yes Reporter is Patient? Title Last name (b)(6) Middle Name First name Number/Street City				
Primary? Yes Reporter is Patient? Title Last name (b)(6) Middle Name First name Number/Street City	Se	ection F - About the Person Fill	ling Out This Form 1 of 1	
Title Last name (b)(6) Middle Name First name Number/Street City (b)(6)				
Last name (b)(6) Middle Name First name Number/Street City		Reporter is Patient?		
Middle Name First name Number/Street City Middle Name (b)(6)		Title		
First name Number/Street (b)(6)		Last name	(b)(6)	
City				
City		First name	(h)(6)	
City		Number/Street		
State/Province		City		
O I	_		LINUTED OTATEO	_
Country UNITED STATES		-		
ZIP or Postal code		ZIP or Postal code	(b)(6)	_
ZIP or Postal code Telephone number Email address Telephone number	1	releptione number		1

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-84341 | Department: CFSAN | RCT No.: RCT-1180195 | CTU Triage Date: 16-Nov-2023 | Total Pag

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	

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:26 Page 5 of 5

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

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

Test Result

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-R	SS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		
<u> </u>	·		

С	ontact			
С	ase First Name eporter	Last Name	Email Address	Phone
V	/I- \/C\	(b)(6)	(b)(6)	(b)(6)
Se	ection A - About the Problem			
	What kind of problem was it? (Check all that apply)	Used a product incorrectly Noticed a problem with the	de effect (including new or worsening symp which could have or led to a problem e quality of the product ing from one product maker to another ma	
	Date the problem occurred	08-Aug-2023		
	Serious	Yes		
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted of Required help to prevent p Disability or health problem Birth defect Life-threatening Death Other serious/important me	permanent harm	
	Other serious/important medical incident(Please Describe Below)			
	Tell us what happened and ho y additional documents if nece		as many details as possible	FDA may reach out to you for
		d mango. I brought him to t		ouree pouches. We had the apple neck up and his lead level was a 2.

R	elevant Test/Laboratory Data			1 of 2	
	Test Name	LEAD	Test Date	11-Nov-2023	

Test Unit

MICROGRAMS PER DEC

ILITRE

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:34 Page 1 of 5

4

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

es: 5

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

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:34 Page 2 of 5

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

	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?			
Wł	ny was the person using the pr	oduct? (such as what con	dition was it supposed to tr	eat) 1 of 1
	Returned to Manufacturer On			
Se	ction D - About the Medical De	evice		
	Name of medical device			
	Name of the company that			
	makes the medical device			
	makes the medical device ner identifying information (The	e model, catalog, lot, seria	ll, or UDI number, and the e	expiration date, if you can
	makes the medical device	e model, catalog, lot, seria	II, or UDI number, and the ϵ	expiration date, if you can
	makes the medical device ner identifying information (The	e model, catalog, lot, seria	ll, or UDI number, and the e	expiration date, if you can
	makes the medical device ner identifying information (The	e model, catalog, lot, seria	ll, or UDI number, and the e	expiration date, if you can
	makes the medical device ner identifying information (The	e model, catalog, lot, seria	II, or UDI number, and the e	expiration date, if you can
	makes the medical device ner identifying information (The	e model, catalog, lot, seria	II, or UDI number, and the e	expiration date, if you can
	makes the medical device ner identifying information (The ate them)	e model, catalog, lot, seria	Il, or UDI number, and the e	expiration date, if you can
	makes the medical device her identifying information (The eate them) Model Number	e model, catalog, lot, seria	II, or UDI number, and the e	expiration date, if you can
	makes the medical device her identifying information (The eate them) Model Number Catalog Number	e model, catalog, lot, seria	Il, or UDI number, and the e	expiration date, if you can
	makes the medical device her identifying information (The eate them) Model Number Catalog Number Lot Number	e model, catalog, lot, seria	I, or UDI number, and the e	expiration date, if you can
	makes the medical device her identifying information (The eate them) Model Number Catalog Number Lot Number Serial Number	e model, catalog, lot, seria	I, or UDI number, and the e	expiration date, if you can
	makes the medical device her identifying information (The eate them) Model Number Catalog Number Lot Number Serial Number UDDI Number	e model, catalog, lot, seria	II, or UDI number, and the e	expiration date, if you can
loc	makes the medical device her identifying information (The eate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem			expiration date, if you can
Fo	makes the medical device her identifying information (The eate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred?			
Fo	makes the medical device her identifying information (The late them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O ate the implant was put in	NLY (such as pacemakers	s, breast implants, etc.) Date the implant was taken ou	
Fo	makes the medical device her identifying information (The late them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O	NLY (such as pacemakers	s, breast implants, etc.) Date the implant was taken ou	
Fo	makes the medical device her identifying information (The rate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? r implanted medical devices O ate the implant was put in ction E - About the Person Wh	NLY (such as pacemakers	s, breast implants, etc.) Date the implant was taken ou	

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

es: 5

	Please Specify Other Gender		
	Age (specify unit of time for age)	(1.) (2)	
	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	
Lis	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	<u> </u>		
ll ic	et any other important informati	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
Ше	st arry other important imormati	on about the person (such as smoking, pregnancy, alcohol use, etc.)	
	.4		
LIS	st all current prescription medic	cations and medical devices being used.	
			_
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
_	Reporter is Patient?		_
	Title		_
	_	(b)(6)	
	Middle Name		
		0)(6)	
1	First name		

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:34 Page 4 of 5

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

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

Generated by: SYSTEM Generated on: 15-Nov-2023 15:15:34 Page 5 of 5

es: 9 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:		(b)(6)		
A2. Age:		2		Year(s)
A2. Date of Birth:				
		Male		Yes
		Female		
A3a. Sex: Enter the patient's sex	at birth	Undifferentiated		
		Decline to answer		
A3b. Gender: Enter the patient's			responds with birth corresponds with	
	g	,	birth sex) Transgender man/trans man/female-to-male (FTM)	
		Transgender woman/trans wom male-to-female (MTF)	an/	
		Other gender category; Please	specify:	
		Decline to answer		
A4. Weight:				
A5. Ethnicity:		Hispanic/Latino		
Ao. Lumoity.		Not Hispanic/Latino		Yes
		Asian		
		American Indian or Alaskan Nat	ive	
A6. Race:		Black or African American		
		White		Yes
		Native Hawaiian or Other Pacific	slander	

· · · · · · · · · · · · · · · · · · ·	Adverse Event	ı	
	Product Use/Medication Error		
B1. Type of Report:	Product Problem (e.g.,	Yes	
Dr. Type of Report.	defects/malfunctions)		
	Problem with Different Manufacturer of		
	Same Medicine		
	Death (Date of Death)		
	Life-threatening	·	
	Hospitalization (initial or prolonged)		
B2. Outcome Attributed to Adverse Event:	Disability or Permanent Damage		
b2. Outcome Attributed to Adverse Event.	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	25-Oct-2023	
B4. Date of this Report:	15-Nov-2023	15-Nov-2023	

	el 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 o	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				
	venous lead level				
Test Name:					
lest Name.					
	9.1				
Test Result:					
1001100010					
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:					
T					
Test Name:					
Test Result:					
rost 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:	
T (B "	
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:	
rest Name.	
Test Result:	
Test Unit:	
Low Test Range:	
High Test Range:	
riigii roscitalige.	

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 test 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?					
<u> </u>					
D. SUSPECT PRODUCTS					
Product 1					
D1. This report involves:	0		1		
bit this report involves.	Cosmetic				
	Dietary supplement				
	Food/medical food		Yes		
	Other				
D1. Name:	WanaBana Apple Cinnamon Fruit Puree	e pouches			
D1. Strength:					
D1. Manufacturer/Compounder:					
D1. NDC # or Unique ID:					
D1. Lot #:					
D2. Dose or Amount:					
D2. Frequency:					
D2. Route:					
	Start	Stop		Dose Reduced	
D3. Treatment Dates/Therapy Dates:	Give best estimate of duration	10.00			
.,	Is therapy still on-going?				
D4. Diagnosis for Use:					
	OTC (Over-the-counter)				
	Compounded				
5. Product Type:	Generic				
	Biosimilar				
	Biosimilai				
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:					
DZ. Noute.	Start	Stop		Dose Reduced	
D3. Treatment Dates/Therapy Dates:	Give best estimate of duration	Stop		Dose Neduced	
D3. Treatment Dates/Therapy Dates.	Is therapy still on-going?	+			
D4. Diagnosis for Use:	is thorapy still on going.				
שבי טומאַוועאַוס ועו טאַכ.	OTC (Over-the-counter)				
	Compounded				
D5. Product Type:	Generic				
	Biosimilar				
D6. Expiration Date:	Diodiffici				
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 P	uree 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) #:			
	Health Professional		
E5. Operator of Device:	Patient/Consumer		
			I
	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?			
Lo. Was this device serviced by a tillid party servicer:			

EU No.: FDA. CDER CTU 2023 84428 Department: CFSAN . OTHER (CONCOMITANT) MEDICAL PRODUCTS Product Name	Therapy Start Date	Therapy End Date
WanaBana Apple Cinnamon Fruit Puree pouches		
2.		
3.		
l.		
j.		
5.		
7.		
3.		
).		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
8.		
9.		
20.		
11.		

G. REPORTER	
	Last Name First Name Address
	First Name
	Address
G1. Name and Address	
	(b)(6)
	State/Province/Region
	ZIP/Postal Code
	Country US
	Phone #: (h)(6)
	Phone #. Email: (b)(6)
G2. Health Professional?	Yes
G3. Occupation:	Nurse
	Manufacturer/Compounder
G4. Also Reported To:	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

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

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

Basic Details	initi-05:00) time zone				
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
	Routine	Source Form Type	EZB XIVIL 3300B		
Priority		T			
Override Auto Calculation Rule	No	OTU D	40.11 0000		
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 First Name	Last Name	Email Address	Phone		
Reporter	/b\/C\	(1.) (0)			
(p)(p)	(p)(p)	(b)(6)			
Section A - About the Problem	<u>'</u>				
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		

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

Generated by: SYSTEM Generated on: 16-Nov-2023 00:45:22 Page 1 of 5

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

es: 5

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the product? (check yes if you are including a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes		- .	
	Primary?	Yes		_	
	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana Apple Cinnamo	on 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 Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		1		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug 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	28-Oct-2023			

Generated by: SYSTEM Generated on: 16-Nov-2023 00:45:22 Page 2 of 5

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

	Date the person reduced dose of the product	28-Oct-2023	
	Give best estimate of duration		
	Is therapy still on-going?		
WI	hy was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	her identifying information (The cate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem occurred?		
Fo	or implanted medical devices C	NLY (such as pacemakers, breast implants, etc.)	
Da	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(b)(6)	
	Sex	Male	
	Gender	Cisgender man/boy	
	Please Specify Other Gender		
	Age (specify unit of time for age)	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	

Generated by: SYSTEM Generated on: 16-Nov-2023 00:45:22 Page 3 of 5

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

es: 5

		White Black or African American	
Lis	st known medical conditions ((Such as diabetes, high blood pressure, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as	s to drugs, foods, pollen or others)	
Lis	st any other important informa	ation about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription med	dications and medical devices being used.	
Lis	st all over-the-counter medica	ations and any vitamins, minerals, supplements, and herbal remedies being use	d.
	<i>c</i>		4
56	ection F - About the Person F		
	Primary? Reporter is Patient?	Yes	_
	Title		
	Last name	(b)(6)	_
	Middle Name		_
	First name	(b)(6)	_
	Number/Street		_
	City		+
	State/Province	(b)(6)	_
	Country	UNITED STATES	
	000.11.7	UNITED STATES	
	ZIP or Postal code	UNITED STATES	
		UNITED STATES	

Generated by: SYSTEM Generated on: 16-Nov-2023 00:45:22 Page 4 of 5

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

es: 5

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	

Generated by: SYSTEM Generated on: 16-Nov-2023 00:45:22 Page 5 of 5

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

All dates displayed in the report are in EST(G	MT-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-OS	E-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct	2 1100 010@1dd.11110.gov) (L2B)	
-			
Contact			
Case First Name	Last Name	Email Address	Phone
Reporter		Littali Address	
(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 s	ide effect (including new or worsening symptor	ms)
(Crieck all triat apply)		ly which could have or led to a problem	
	Noticed a problem with the	ne quality of the product	
	Had problems after switch	hing from one product maker to another maker	r
Date the problem occurred	20-Oct-2023		
Serious	Yes		
Did any of the following happen?	Hospitalization - admitted	d or stayed longer	
(Check all that apply)	Required help to prevent	permanent harm	
	Disability or health proble	em	
	Birth defect		
	Life-threatening		
	Death		
	Other serious/important r	medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)			
4.Tell us what happened and how any additional documents if nece	w it happened (Include essary)	e as many details as possible F	DA may reach out to you for
		affected) purchased WanaBana Cinna	
Tree in (b)(6) My sons ages 2.5 years and 15 m		ased were from LOT 02023:18 15:13 / 2 pouches each of the fruit puree po	
		tested for lead at their regular check	

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.

ĮR	elevant Test/Laboratory Data			1 of 1	
	Test Name	LEAD	Test Date	31-Oct-2023	

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:34 Page 1 of 5

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

es: 5

	T .				-
	Test Result	4	Test Unit	MICROGRAMS PER DEC	
	Low Test Range	0	High Test Range		
	More Information Available?				
٩c	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are	No			
	including a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
	Name of the product as it	WanaBana Apple Cinnamor	n fruit puree		
	appears on the box, bottle, or package (Include as many				
	names as you see)				
	Name of the company that makes (or compounds) the	WanaBana			
	product				
	Product Type(check all that	Over-the-Counter			
	apply)	Compounded by a Pharmacy of	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	Doesn't Apply			
	person started taking or using the				
٦r	product again? ug Therapy			1 of 1	
<u>ا</u> ر	Expiration date	18-Apr-2024		1011	
	Lot number	02023:18 15:13			
	Dosage Form	32320.10 10.10			
	Quantity	Other	If Other	2 Pouches	
	Frequency		If Other		
	How was it taken or used	Oral	If Other		

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:34 Page 2 of 5

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

	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?			
WI	hy was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot		e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
	cate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem occurred?			
Fο	or implanted medical devices O	NLY (such as pacemaker	rs breast implants etc.)	
	ate the implant was put in	TTET (Bush us pusernans)	Date the implant was taken out (If	
			relevant)	
Se	ection E - About the Person Wh	o Had the Problem		
	Person's Initials	(b)(6)		
	Sex	Male		
	Gender	Cisgender man/boy		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b)(6)		
	Weight	12.6 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		+

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:34 Page 3 of 5

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

	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	
		Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
Г			
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or others)	
LIS	st any other important informati	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
ll is	st all current prescription medic	cations and medical devices being used.	
	st air carrent procenpactr means	ations and medical devices semiglassa.	Τ
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
	Probiotic, Vitamin C, Childrens mu		T
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		+
	Title		+
	Last name	(b)(6)	+
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
1	ZIP or Postal code	(b)(6)	

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:34 Page 4 of 5

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

Telephone number	(h)(6)	
Email address	(b)(6)	T
Fax		Г
Reporter Organization		Г
Department		Г
Reporter Speciality		T
Today's date	16-Nov-2023	T
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	

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:34 Page 5 of 5

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

Other serious/important medical incident(Please Describe Below)

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-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		
Case Reporter First Name (b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A - About the Problem			
What kind of problem was it? (Check all that apply)	Used a product incorre	d side effect (including new or worsening sympto ectly which could have or led to a problem in the quality of the product itching from one product maker to another make	
Date the problem occurred	20-Oct-2023		
Serious	Yes		
Did any of the following happer (Check all that apply)	Hospitalization - admitt Required help to preve Disability or health prol Birth defect Life-threatening Death	ent permanent harm	

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

Other serious/important medical incident(Please Describe Below)

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 . 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.

R	elevant Test/Laboratory Data			1 of 1	
	Test Name	LEAD	Test Date	31-Oct-2023	

Generated by: SYSTEM 16-Nov-2023 20:45:29 Page 1 of 5 Generated on:

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

es: 5

	Test Result	5	Test Unit	MICROGRAMS PER DEC	
	Low Test Range	0	High Test Range		
	More Information Available?			,	
Ad	lditional Comments				
Co	pation D. Draduct Availability				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the product? (check yes if you are	No			
	including a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Food/Medical food			
	Name of the product as it	WanaBana Apple Cinnamor	n fruit puree		
	appears on the box, bottle, or package (Include as many				
	names as you see)				
	Name of the company that makes (or compounds) the	WanaBana			
	product				
	Product Type(check all that apply)	Over-the-Counter			
	арріу)	Compounded by a Pharmacy of	or an Outsourcing Facility		
		Generic			
	Strength	Biosimilar	If Other		_
	NDC number		ii Otiloi		
	Did the problem stop after the				_
	person reduced the dose or				
	stopped taking or using the product?				
	Did the problem return if the	Doesn't Apply			_
	person started taking or using the product again?				
Dr	ug 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		

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:29 Page 2 of 5

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

	es. J				
	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			
W	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to treat)	1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot	ther identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the expira	tion date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
L	Serial Number				
L	UDDI Number				
L	Expiration date				
	Was someone operating the medical device when the problem occurred?				
ļΕο	or implanted medical devices O	NLY (such as pacemake	rs, breast implants, etc.)		
D	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	o Had the Problem			
	Person's Initials	(b)(6)			
	Sex	Male			
\vdash	Gender	Cisgender man/boy			
\vdash	Please Specify Other Gender				
\vdash	Age (specify unit of time for age)				
\vdash	Date of Birth	(b)(6)			

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:29 Page 3 of 5

15.75 kg

Not Hispanic/Latino

Weight

Ethnicity (Choose only one)

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

	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
ĮΡŀ	ease list all allergies (such as t	o drugs, foods, pollen or others)	
Lis	st any other important informati	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices being used.	
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used	
	Probiotic, Vitamin C, Childrens mu	ultivitamin	
ΙSε	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	\top
	Reporter is Patient?		_
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	b)(6)	

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

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

Generated by: SYSTEM Generated on: 16-Nov-2023 20:45:29 Page 5 of 5

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

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

IPasia Dataila					
Basic Details Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium					
Priority Priority	MWO (Drug) Source Form Type E2B XML 3500 Routine				
Override Auto Calculation Rule	No				
		CTU De seiser d De te	47 Nov. 2022		
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 First Name Reporter	Last Name	Email Address	Phone		
(b)(6)	(b)(6)	(b)(6)	(b)(6)		
	(12)(12)		(10)(10)		
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, PRODUC	T 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 pro Other Serious or Important Disability or Permanent Da	Medical Events			

Generated by: SYSTEM Generated on: 17-Nov-2023 12:15:29 Page 1 of 4

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

		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			
De	escribe Event, Problem or Prod	luct 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.				
Re	elevant Test/Laboratory Data			1 of 1	
	Test Name	LEAD BLOOD (PEDIATRI C) VENOUS	Test Date	10-Nov-2023	
	Test Result	6.4	Test Unit	MICROGRAMS PER DEC	
	Low Test Range	0.0	High Test Range	3.4	
	More Information Available?				
Ad	ditional Comments				
Otl	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			
	Туре	Drug/Biologic			
	This report involves:	Food/Medical food			
Na	me,Strength,Manufacturer/Co	mpounder (from product I	abel)		
	Product Name Wana Bana Apple Cinnamon Fruit Puree Pouches				
	Strength	ngth If Other			
	Manufacturer/Compounder	Wana Bana-Austrofood			

Generated by: SYSTEM Generated on: 17-Nov-2023 12:15:29 Page 2 of 4

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

	NDC# or Unique ID				
	Product Type(check all that	Отс		-	
	apply)	Compounded			
		Generic			
		Biosimilar			
	Event Abated After Use Stopped				
	or Dose Reduced?				
	Event Reappeared after Reintroduction ?				
Dr	rug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency	Other	If Other	Whenever	
	Route		If Other		
	Dosage Form			J	
	Start			-	
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?	No		J	
	Lot Number	01023:23			
	Expiration Date	23-Mar-2024			
Di	agnosis for Use (indication)			1 of 1	
F	SUSPECT MEDICAL DEVICE				
	Brand Name	<u>- </u>			
	Common Device Name				
	Procode				
	Manufacturer Name				
	City				
	State				
_	Model #				
	Lot#				
	Catalog #				
	Expiration Date				
	Serial #				
	Unique Identifier (UDI)#				
	Operator of Device				
	Operator or Device	Health Professional			
		Patient/Consumer			
	Other	Other			
	If Implanted, Give Date				
					1

Generated by: SYSTEM Generated on: 17-Nov-2023 12:15:29 Page 3 of 4

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

	If Explanted, Give Date				
	Is this a single-use device that was reprocessed and reused on a patient?				
	If Yes for the above field, Enter Name and Address of Reprocessor				
	Was this device serviced by a third party?				
E	OTHER (CONCOMITANT) ME	DICAL DRODUCTS			
Г.	OTHER (CONCOMITANT) ME CONCOMITANT MEDICAL PROD				
	OCHOCKITATE MEDICAL FROM	Der Bestar Horr			
	DEDODTED			1 -51	
G.	REPORTER Primary?	Yes		1 of 1	
	Reporter is Patient?	165			
	Title				
		b)(6)			
	Middle Name				
	_	(L)(C)			
	Address	(b)(6)			
	City	(-) (-)			
	State/Province/Region				
	Country	UNITED STATES	If Other		
	ZIP/Postal Code	(b)(C)			
	Phone	(b)(6)			
	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			

Generated by: SYSTEM Generated on: 17-Nov-2023 12:15:29 Page 4 of 4

