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	