

More Information Available?	
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Additional Comments

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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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar
Strength	<input type="text"/> If Other <input type="text"/>
NDC number	<input type="text"/>
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	<input type="text"/>
Lot number	<input type="text"/>
Dosage Form	<input type="text"/>
Quantity	<input type="text"/> If Other <input type="text"/>
Frequency	Twice a day If Other <input type="text"/>
How was it taken or used	Oral If Other <input type="text"/>
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	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian

		<input type="checkbox"/>	White	
		<input checked="" type="checkbox"/>	Black or African American	

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

	N/A
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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.)

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List all current prescription medications and medical devices being used.

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

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



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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input checked="" type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input checked="" type="checkbox"/> Generic <input type="checkbox"/> Biosimilar
Strength	<input type="text"/> If Other <input type="text"/>
NDC number	<input type="text"/>
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?	<input type="text"/>

Drug Therapy 1 of 1

Expiration date	09-Jul-2024
Lot number	05023:09
Dosage Form	<input type="text"/>
Quantity	<input type="text"/> If Other <input type="text"/>
Frequency	Daily If Other <input type="text"/>
How was it taken or used	<input type="text"/> If Other <input type="text"/>
Date the person first started taking or using the product	<input type="text"/>
Date the person stopped taking or using the product	<input type="text"/>
Date the person reduced dose of the product	<input type="text"/>

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	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> 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	(b)(6)	
City	(b)(6)	
State/Province	(b)(6)	
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number	(b)(6)	
Email address	(b)(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	



KOSHER

**WANA
BANA**

Net Weight:
7.50 oz
(213 g)

**APPLE
CINNAMON**

FRUIT PUREE

- No preservatives
- Gluten free

**3
PACK**



Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	4%
Carbohydrate 12g	7%
Dietary Fiber 2g	
Total Sugars 9g	
Includes 0g Added Sugars	0%
<hr/>	
Vitamin D 0mcg	0%
Iron 4mg	0%
Calcium 0mg	0%
Vitamin A 60mcg	0%

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

Ingredients: Apple puree, cinnamon powder, citric acid.

READY TO EAT FOR MICROWAVE
Produced / 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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input checked="" type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input checked="" type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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?	
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Additional Comments

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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)	<input checked="" type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar
Strength	<input type="text"/> If Other <input type="text"/>
NDC number	<input type="text"/>
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	<input type="text"/>
Lot number	<input type="text"/>
Dosage Form	<input type="text"/>
Quantity	<input type="text"/> If Other <input type="text"/>
Frequency	<input type="text"/> If Other <input type="text"/>
How was it taken or used	<input type="text"/> If Other <input type="text"/>
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	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian

	<input checked="" type="checkbox"/>	White	
	<input type="checkbox"/>	Black or African American	

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

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

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

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List all current prescription medications and medical devices being used.

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

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

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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> 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	
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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

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Returned to Manufacturer On	
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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)

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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> White <input checked="" type="checkbox"/> Black or African American

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

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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.

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

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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	(b)(6)	
Country	UNITED STATES	
ZIP or Postal code	(b)(6)	
Telephone number	(b)(6)	
Email address	(b)(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	

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
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A. PATIENT INFORMATION			
A1. Patient Identifier:	(b)(6)		
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 (<i>Date of Death</i>)		
	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 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?	

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	(b)(6)
	Address	(b)(6)
	City	(b)(6)
	State/Province/Region	(b)(6)
	ZIP/Postal Code	(b)(6)
	Country	US
	Phone #:	(b)(6)
	Email:	(b)(6)
G2. Health Professional?	Yes	
G3. Occupation:	Nurse	
G4. Also Reported To:	Manufacturer/Compounder	
	User Facility	
	Distributor/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	<input checked="" type="checkbox"/>		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input type="checkbox"/> 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?	
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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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> Biosimilar
Strength	<input type="text"/> If Other <input type="text"/>
NDC number	<input type="text"/>
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	<input type="text"/>
Lot number	<input type="text"/>
Dosage Form	<input type="text"/>
Quantity	<input type="text"/> If Other <input type="text"/>
Frequency	<input type="text"/> If Other <input type="text"/>
How was it taken or used	Oral If Other <input type="text"/>
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

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Returned to Manufacturer On	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian

<input checked="" type="checkbox"/> White
<input type="checkbox"/> 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.

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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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)

<p>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.</p>
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Relevant Test/Laboratory Data			
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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> 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

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Returned to Manufacturer On	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American
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List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

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

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

List all current prescription medications and medical devices being used.

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

Probiotic, Vitamin C, Childrens multivitamin

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

Telephone number	(b)(6)	
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)?	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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(b)(6)	(b)(6)	(b)(6)	(b)(6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	<input checked="" type="checkbox"/> Were hurt or had a bad side effect (including new or worsening symptoms) <input type="checkbox"/> Used a product incorrectly which could have or led to a problem <input type="checkbox"/> Noticed a problem with the quality of the product <input type="checkbox"/> 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)	<input type="checkbox"/> Hospitalization - admitted or stayed longer <input type="checkbox"/> Required help to prevent permanent harm <input type="checkbox"/> Disability or health problem <input type="checkbox"/> Birth defect <input type="checkbox"/> Life-threatening <input type="checkbox"/> Death <input checked="" type="checkbox"/> 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)

<p>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.</p>
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Relevant Test/Laboratory Data			
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

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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)	<input type="checkbox"/> Over-the-Counter <input type="checkbox"/> Compounded by a Pharmacy or an Outsourcing Facility <input type="checkbox"/> Generic <input type="checkbox"/> 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

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Returned to Manufacturer On	
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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)	
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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)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American
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List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

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

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

List all current prescription medications and medical devices being used.

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

Probiotic, Vitamin C, Childrens multivitamin

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

Telephone number	(b)(6)	
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)?	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	<input checked="" type="checkbox"/> CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
<input checked="" type="checkbox"/>	(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)	<input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Black or African American <input checked="" type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	<input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Use/Medication Error <input checked="" type="checkbox"/> Product Problem (e.g., defects/malfunctions) <input type="checkbox"/> Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	<input type="checkbox"/> Death <input type="checkbox"/> Life Threatening <input type="checkbox"/> Hospitalization (initial or prolonged) <input checked="" type="checkbox"/> Other Serious or Important Medical Events <input type="checkbox"/> Disability or Permanent Damage

	<input type="checkbox"/> Congenital Anomaly/Birth Defects	
	<input type="checkbox"/> 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)	<input type="checkbox"/> OTC <input type="checkbox"/> Compounded <input type="checkbox"/> Generic <input type="checkbox"/> 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	<input type="checkbox"/> Health Professional <input type="checkbox"/> Patient/Consumer <input type="checkbox"/> 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

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G. REPORTER 1 of 1

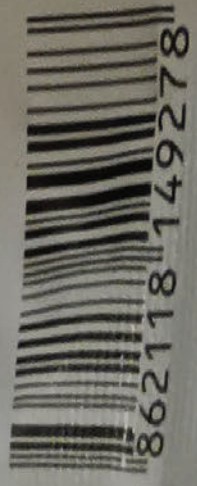
Primary?	Yes	
Reporter is Patient?		
Title		
Last Name	(b)(6)	
Middle Name		
First Name	(b)(6)	
Address	(b)(6)	
City	(b)(6)	
State/Province/Region	(b)(6)	
Country	UNITED STATES	If Other
ZIP/Postal Code	(b)(6)	
Phone	(b)(6)	
Email	(b)(6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality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

Manufactured by CALISTROFOOD S.A.S. Av. Gen. Enriquez y Mikuchi (Esq.), Quito Ecuador. Imported in USA by: Wanabana Wanabana USA, LLC 2713 W. Jackson - Jacksonville FL 32209. Tel: 904-88-272-7184 Fax: 904-88-272-7184 Email: info@wanabana.com

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: 03-23-2024
LOT: 01029 23 16:59

