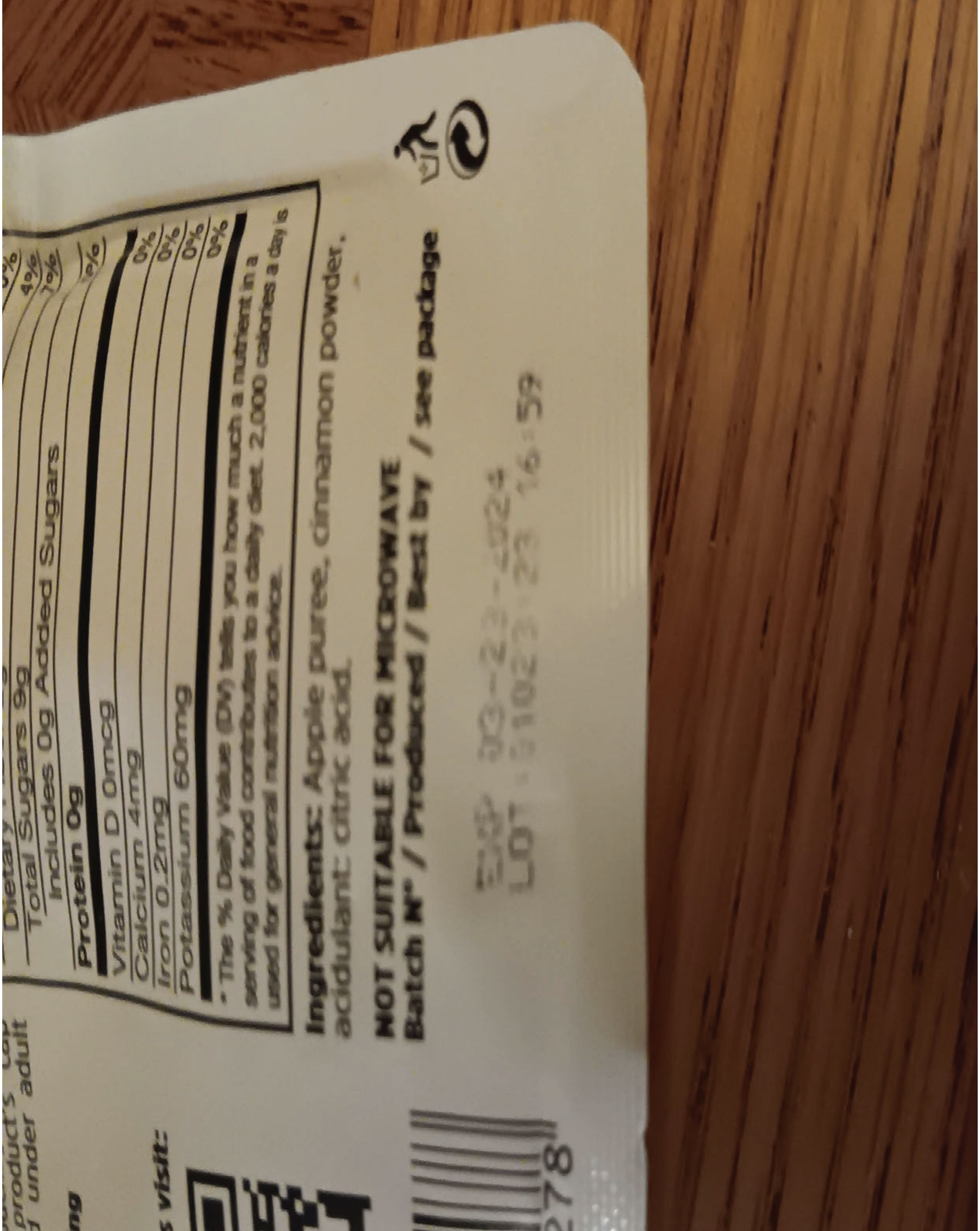

Total Sugars 9g
Includes 0g Added Sugars 7%
Protein 0g
Vitamin D 0mcg 0%
Calcium 4mg 0%
Iron 0.2mg 0%
Potassium 60mg 0%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.
Ingredients: Apple puree, cinnamon powder, acidulant: citric acid.
NOT SUITABLE FOR MICROWAVE
Batch N° / Produced / Best by / see package
EXP 03-23-2024

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

Basic Details

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

Contact

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

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

Describe Event, Problem or Product Use Error

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

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

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

Other Relevant History, Including Preexisting Medical Conditions

No pre-existing health conditions reported by mother.

C. PRODUCT AVAILABILITY

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

D. PRODUCT(S) 1 of 1

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

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

	Product Name	Wana Bana Apple Cinnamon Fruit Puree

Strength	233 G gram(s)	If Other		
Manufacturer/Compounder	Wana Bana			
NDC# or Unique ID				
Product Type(check all that apply)	☑ OTC ☐ Compounded ☐ Generic ☐ Biosimilar			
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			

Drug Therapy 1 of 1

Dose or Amount		If Other		
Frequency		If Other		
Route	Oral	If Other		
Dosage Form				
Start				
Stop				
Dose Reduced				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

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

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

Basic Details

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

Contact

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

Section A - About the Problem

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

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

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

Relevant Test/Laboratory Data 1 of 4

Test Name	LEAD CAPILLARY	Test Date	20-Sep-2023
Test Result	21.5	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 4

Test Name	LEAD BLOOD VENOUS	Test Date	28-Sep-2023
Test Result	21.0	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 3 of 4

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

Relevant Test/Laboratory Data 4 of 4

Test Name	LEAD BLOOD VENOUS	Test Date	25-Oct-2023
Test Result	25.4	Test Unit	MICROGRAMS PER DECILITRE
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Food/Medical food
Name of the product as it appears on the box, bottle,	WanaBana apple cinnamon fruit Puree pouches

	or package (Include as many names as you see)			
	Name of the company that makes (or compounds) the product	Wanabana		
	Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	Strength		If Other	
	NDC number			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
	Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

	Expiration date	30-Mar-2024		
	Lot number	01023:30		
	Dosage Form			
	Quantity	Other	If Other	1 7.50oz
	Frequency	Other	If Other	Every day
	How was it taken or used	Oral	If Other	
	Date the person first started taking or using the product	10-Oct-2022		
	Date the person stopped taking or using the product	19-Oct-2023		
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?	Yes		

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

	Hunger/nutrition

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

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

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

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

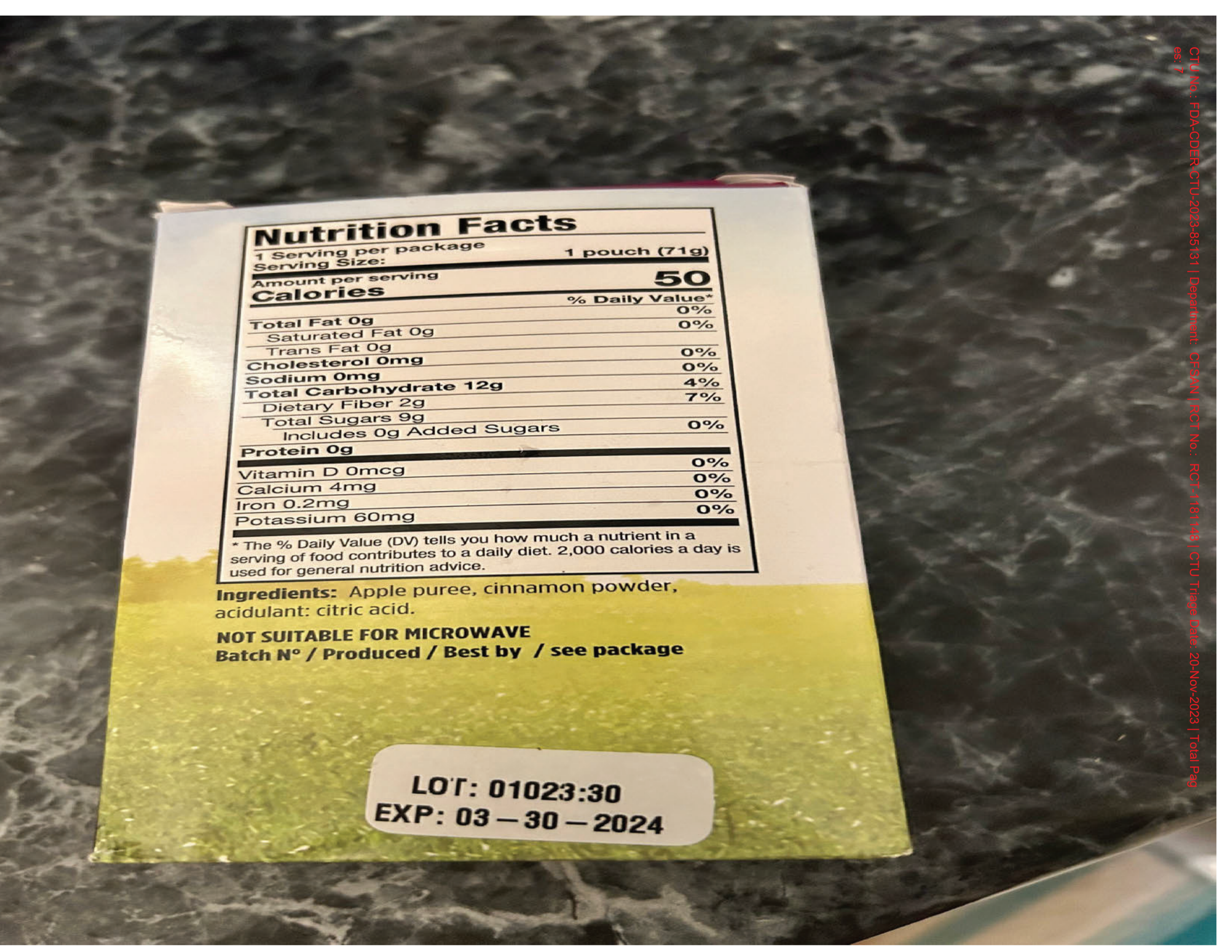
List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

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

Section F - About the Person Filling Out This Form 1 of 1

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



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

Basic Details

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

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	23-Aug-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

My daughter, (b)(6) (now 15.5 month old), was gifted approximately 6 WanaBana apple cinnamon fruit puree pouches on 08/05/2023. She consumed these over the next few weeks. At her 12-month well child check on 08/23/2023, she had her blood lead level checked. Her first toe prick (capillary) BLL result was 6.2 ug/dL, and it was confirmed by a second toe prick on the same day. To verify accuracy, she had a repeat BLL done by venous draw on 08/24/2023, with a result of 6.4 ug/dL. We live in a house built in 1952, so we assume it was an issue with our home. Our water testing came back negative for lead. Our paint testing came back with few areas of concern (and most did not have deteriorating paint prior to testing). We assumed the lead must have been present in some sort of baby food, or baby toy, as my husband and my own BLL tests came back negative as well. Everything clicked when we saw the recall alert for WanaBana apple cinnamon fruit puree pouches with our local news station. Luckily, our daughter seemed asymptomatic during this period of time and we only had a few of these pouches in our home. Without changing anything, home- or diet-wise, (other than no longer eating these pouches) our daughter's blood lead level has started to decrease. As of 10/30/2023, her blood lead level has dropped to 2.2 ug/dL.

Relevant Test/Laboratory Data 1 of 3

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

Relevant Test/Laboratory Data 2 of 3

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

Relevant Test/Laboratory Data 3 of 3

	Test Name	LEAD, BLOOD (PEDS) VENOUS	Test Date	30-Oct-2023	
	Test Result	2.2	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0.0 ug/dL	High Test Range	3.4 ug/dL	
	More Information Available?				

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	Drug/Biologic
	This report is about	Food/Medical food
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple cinnamon fruit puree pouches
	Name of the company that makes (or compounds) the product	WanaBana
	Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility

		☐ Generic ☐ Biosimilar		
	Strength		If Other	
	NDC number			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?			
	Did the problem return if the person started taking or using the product again?			

Drug Therapy 1 of 1

	Expiration date			
	Lot number			
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used		If Other	
	Date the person first started taking or using the product	05-Aug-2023		
	Date the person stopped taking or using the product	01-Sep-2023		
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?			

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

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	

Expiration date		
Was someone operating the medical device when the problem occurred?		

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

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

Section E - About the Person Who Had the Problem

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

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

Elevated blood lead level. Plagiocephaly.

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

None known.

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

List all current prescription medications and medical devices being used.

None.

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

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

Basic Details

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

Contact

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

A. PATIENT INFORMATION

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

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

Describe Event, Problem or Product Use Error

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

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

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

D. PRODUCT(S) 1 of 1

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

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

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

NDC# or Unique ID	
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount	180 G gram(s)	If Other	
Frequency	Daily	If Other	
Route	Oral	If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

1 of 1

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

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

Basic Details

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

Contact

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

Section A - About the Problem

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

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

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

Relevant Test/Laboratory Data 1 of 6

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

	More Yn1brmation Available?				
Relevant Test/Laboratory Data					**2 o1l**
	Test Name	LEADx6ENOUS	Test Date	14-Nov-2023	
	Test Result	7	Test Unit	MYLLYGRAMS PER DECYL YTRE	
	Lof Test Range		High Test Range		
	More Yn1brmation Available?				
Relevant Test/Laboratory Data					**3 o1l**
	Test Name	HEMATOCRYT	Test Date	14-Nov-2023	
	Test Result	28w8	Test Unit	PERCENT	
	Lof Test Range		High Test Range		
	More Yn1brmation Available?				
Relevant Test/Laboratory Data					**4 o1l**
	Test Name	HEMATOCRYT	Test Date	03-Nov-2023	
	Test Result	32w	Test Unit	PERCENT	
	Lof Test Range		High Test Range		
	More Yn1brmation Available?				
Relevant Test/Laboratory Data					**5 o1l**
	Test Name	HEMOGLOBYN	Test Date	03-Nov-2023	
	Test Result	11	Test Unit	GRAMS PER DECYLYTER	
	Lof Test Range		High Test Range		
	More Yn1brmation Available?				
Relevant Test/Laboratory Data					**l o1l**
	Test Name	HEMOGLOBYN	Test Date	14-Nov-2023	
	Test Result	10w2	Test Unit	GRAMS PER DECYLYTER	
	Lof Test Range		High Test Range		
	More Yn1brmation Available?				

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 o11

	Suspect	Yes		
	Primary?	Yes		
	Type	Drug/Biologic		
	This report is about	Food/Medical 1bod		
	Name o1the product as it appears on the bo4xbottlex or package (Yclude as many names as you see)	Wana bana cinnamon apple puree 3 pack		
	Name o1the company that makes (or compounds) the product	Wana bana		
	Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
	Strength		Y1Other	
	NDC number			
	Did the problem stop a1ter the person reduced the dose or stopped taking or using the product?			
	Did the problem return i1the person started taking or using the product again?			

Drug Therapy 1 o11

	E4piration date			
	Lot number			
	Dosage Form			
	Vuantity		Y1Other	
	Frequency		Y1Other	
	Hof f as it taken or used	Oral	Y1Other	
	Date the person 1rst started taking or using the product	25-Sep-2023		
	Date the person stopped taking or using the product	20-Oct-2023		
	Date the person reduced dose o1 the product			
	Give best estimate o1duration			
	Ys therapy still on-going?			

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

	Returned to Manu1acturer On	

Section D - About the Medical Device

	Name o1medical device	

Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

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

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

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

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

List all current prescription medications and medical devices being used.
Prescription iron supplement started 11/18

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

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

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

Basic Details

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

Contact

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b)(6)
	Age	21 Month(s)
	Date of Birth	
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Weight	10.2 kg
	Ethnicity (Check single best answer)	Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

Describe Event, Problem or Product Use Error

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

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

venous draw

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

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

D. PRODUCT(S) 1 of 1

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

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

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

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

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

1 of 1

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

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	31-Oct-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

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

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

Relevant Test/Laboratory Data 1 of 1

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

More Information Available?	

Additional Comments

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

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wanabana Apple cinnamon applesauce pouch		
Name of the company that makes (or compounds) the product	Wanabana		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	23-Jun-2024		
Lot number	0402323		
Dosage Form			
Quantity	Other	If Other	14 Pouches
Frequency	Twice a day	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	15-Oct-2023		
Date the person stopped taking or using the product	31-Oct-2023		

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

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

Food he likes to eat

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	15.75 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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

Autism level 2

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

None

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

Dev. Delays

List all current prescription medications and medical devices being used.

Guanfacine

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

Polyvisol

Section F - About the Person Filling Out This Form 1 of 1

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

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APPLE CINNAMON FRUIT PURE

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No preservatives
Gluten free

NO SUGAR ADDED

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Net Weight: 2.50 oz (70 g)

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Basic Details

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

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	19-Nov-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

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

Relevant Test/Laboratory Data 1 of 1

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

More Information Available?	

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WANABANA APPLE CINAMON PAUCH		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	19-Nov-2023		
Date the person stopped taking or using the product			

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

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

	Returned to Manufacturer On		

Section D - About the Medical Device

	Name of medical device		
	Name of the company that makes the medical device		

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Not selected
	Gender	Not selected
	Please Specify Other Gender	
	Age (specify unit of time for age)	
	Date of Birth	
	Weight	
	Ethnicity (Choose only one)	
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☐ White ☐ Black or African American

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

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

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

List all current prescription medications and medical devices being used.

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

Section F - About the Person Filling Out This Form 1 of 1

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

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

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

Basic Details

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

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	15-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

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

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

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

Section B - Product Availability

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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Food/Medical food
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Cinnamon Applesauce
Name of the company that makes (or compounds) the product	Wana Bana
Product Type(check all that apply)	☑ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar
Strength	If Other
NDC number	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes
Did the problem return if the person started taking or using the product again?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity	Other	If Other	3 Pouch
Frequency	As needed	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Date the person reduced dose of the product			

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

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

Food

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	15.75 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Please list all allergies (such as to drugs, foods, pollen or others)
None

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
She ate a *lot* of the applesauce.

List all current prescription medications and medical devices being used.
Albuterol

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

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

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

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

Basic Details

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

Contact

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

Section A - About the Problem

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

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

child tested for elevated lead levels related to wanabana fruit pouches

Relevant Test/Laboratory Data 1 of 2

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

	More Information Available?				

Relevant Test/Laboratory Data 2 of 2

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

Additional Comments

lead level improved with removal of WanaBana pouches

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date	
	Lot number	

	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	01-Jan-2023			
	Date the person stopped taking or using the product	26-Oct-2023			
	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				

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

	it is a snack for children - in her lunch

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

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

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

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

Section E - About the Person Who Had the Problem

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

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

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

none

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

none

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

none

List all current prescription medications and medical devices being used.

none

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

none

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b)(6)
Middle Name	
First name	(b)(6)
Number/Street	

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

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

Basic Details

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

Contact

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

Section A - About the Problem

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

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

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

Relevant Test/Laboratory Data 1 of 1

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

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

Additional Comments

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

Section B - Product Availability

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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	Drug/Biologic		
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	WanaBana apple cinnamon fruit puree pouch		
	Name of the company that makes (or compounds) the product	Weis, WanaBana, Schnucks		
	Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☑ Biosimilar		
	Strength		If Other	
	NDC number			
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
	Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

	Expiration date	30-Nov-2023		
	Lot number			
	Dosage Form			
	Quantity	Other	If Other	3 pouch
	Frequency	3 times a day	If Other	
	How was it taken or used	Oral	If Other	
	Date the person first started taking or using the product	14-Sep-2023		