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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	22-Aug-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

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

Relevant Test/Laboratory Data 1 of 5

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

Relevant Test/Laboratory Data 2 of 5

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

Relevant Test/Laboratory Data 3 of 5

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

Relevant Test/Laboratory Data 4 of 5

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

Relevant Test/Laboratory Data 5 of 5

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

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes	

	Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date	31-Dec-2023		
	Lot number	10022:31 08:10		
	Dosage Form			
	Quantity	Other	If Other	2.5 Ounce(s)
	Frequency	Other	If Other	4-6 pouches/day
	How was it taken or used	Oral	If Other	
	Date the person first started taking or using the product	01-May-2023		
	Date the person stopped taking or using the product	31-Aug-2023		
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?			

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

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

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	11.61 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Elevated Blood Lead Level

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

N/a

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

N/A

List all current prescription medications and medical devices being used.

N/A

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

Poly-Vi-Sol

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

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b)(6)
Middle Name	
First name	(b)(6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	30-Oct-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the	No

	manufacturer, please mark this box (Confidentiality Requested):		

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Oct-2023	CTU Received Date	30-Oct-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	09-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

My child was one year old 10/7/23 and had for several weeks started to eat applesauce Loved this particular brand. Would eat 2-3 a day. On 10/9/23 we had his one year check up and found out he was severely anemic. The loose stools (initially thought was caused by breast milk) turned into explosive diarrhea that smelled like death He was having these stools 3-4 times a day Then I saw This recall Our pcp wants to wait 3-4 weeks to do a blood test. But we will definitely be doing one.

Relevant Test/Laboratory Data 1 of 1

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

	More Information Available?	

Additional Comments

PCP is (b)(6)

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date	21-Sep-2024		
	Lot number	07023211542		
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used		If Other	
	Date the person first started taking or using the product	01-Aug-2023		
	Date the person stopped taking or using the product	30-Oct-2023		

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

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

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Male
	Gender	Not selected
	Please Specify Other Gender	
	Age (specify unit of time for age)	1 Year(s)
	Date of Birth	
	Weight	12.6 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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

None

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

None

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

None

List all current prescription medications and medical devices being used.

None

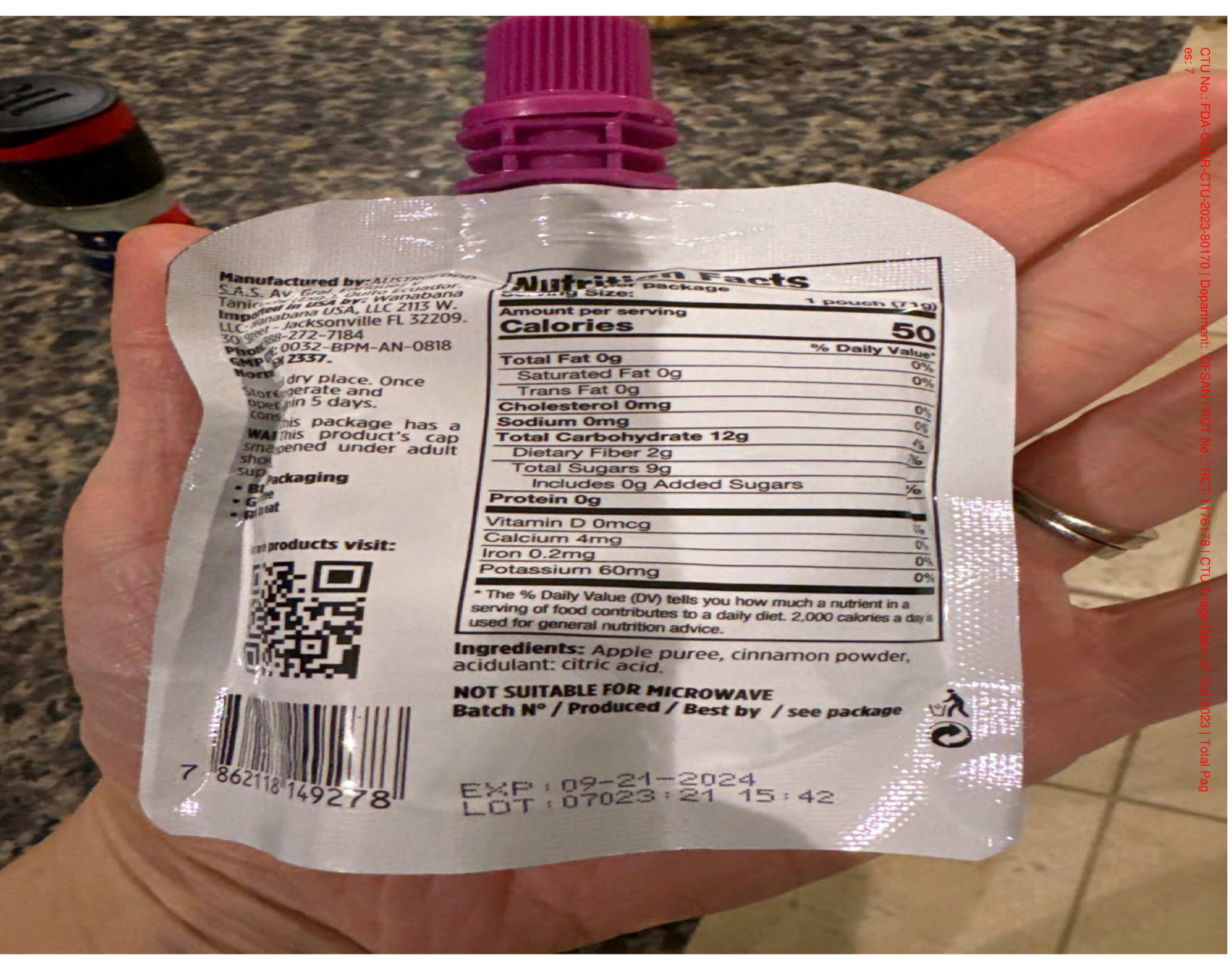
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

None

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

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

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	30-Oct-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	01-Nov-2023	CTU Received Date	01-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

Section A - About the Problem

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

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

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

Relevant Test/Laboratory Data 1 of 2

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

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

Relevant Test/Laboratory Data 2 of 2

	Test Name	LEAD BLOOD TEST	Test Date	11-Sep-2023	
	Test Result	8.5 mcg/dL	Test Unit		
	Low Test Range	< 3.5	High Test Range		
	More Information Available?				

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date	
	Lot number	

	Dosage Form				
	Quantity		If Other		
	Frequency	Twice a day	If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of the product				
	Give best estimate of duration	7 Month			
	Is therapy still on-going?				

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

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

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

Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	11.7 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☑ Black or African American

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

N/A

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

N/A

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

N/A

List all current prescription medications and medical devices being used.

N/A

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

N/A

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

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

	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	01-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	


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

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	03-Nov-2023	CTU Received Date	03-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b)(6)
	Age	17 Month(s)
	Date of Birth	
	Sex	Female
	Gender	Decline to answer
	Please Specify Other Gender	
	Weight	9 kg
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☑ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

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

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: was eating WanaBana fruit pouches. family heard of recall and obtained lead level: 11/1 result 10.8; of note prior lead obtained for routine screening 5/16/23 was <1. These were both venous lead levels

Relevant Test/Laboratory Data 1 of 1

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

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

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

D. PRODUCT(S) 1 of 1

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

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

Product Name	WanaBana fruit pouch		
Strength		If Other	
Manufacturer/Compounder			

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

Drug Therapy 1 of 1

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

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

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

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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

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

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	03-Nov-2023	CTU Received Date	04-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	24-Oct-2023
	Serious	No
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

I made a 1st time purchase of WanaBana cinnamon applesauce from Dollar Tree for my 1 year old. The next day 10/25/23 his babysitter reported to me that he didn't have much of an appetite all day. The following morning 10/26/23 my son woke up an 5am vomiting. I called my sons pediatrician to make an appointment. They advised me to watch my son closely over the weekend for signs of dehydration, if no improvement by Monday they would see him in clinic. He had vomiting and diarrhea over the weekend. He was seen at her pediatricians office Monday Oct 30 where he was diagnosed with the stomach flu. When I returned home I laid my son down for a nap. After doing so I got online and saw a news article about an Urget recall for WanaBana apple cinnamon pouches. Immediately I called his doctor back to report my concern. I left a message with the front office and waited for a response. In the meantime I took my son to the lab at the hospital to have bloodwork done for his lead levels. I had previous doctor orders from my sons 1 year wellness visit. I received his results today and hid lead levels were above range. His pediatrician just recommended retesting in January. My sons symptoms did resolve on Wednesday 11/1/23. No reoccurring symptoms since. I am concerned his flu like symptoms were from the lead exposure in this recalled product.

Relevant Test/Laboratory Data 1 of 1

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

Test Result	4.2	Test Unit	GRAMS PER LITRE	
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

Expiration date	25-Jun-2024			
Lot number	04023 25			
Dosage Form				
Quantity		If Other		
Frequency		If Other		
How was it taken or used		If Other		

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

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

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Age (specify unit of time for age)	
	Date of Birth	(b)(6)
	Weight	9.9 kg
	Ethnicity (Choose only one)	Hispanic/Latino

Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

N/A

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

NKDA

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

List all current prescription medications and medical devices being used.

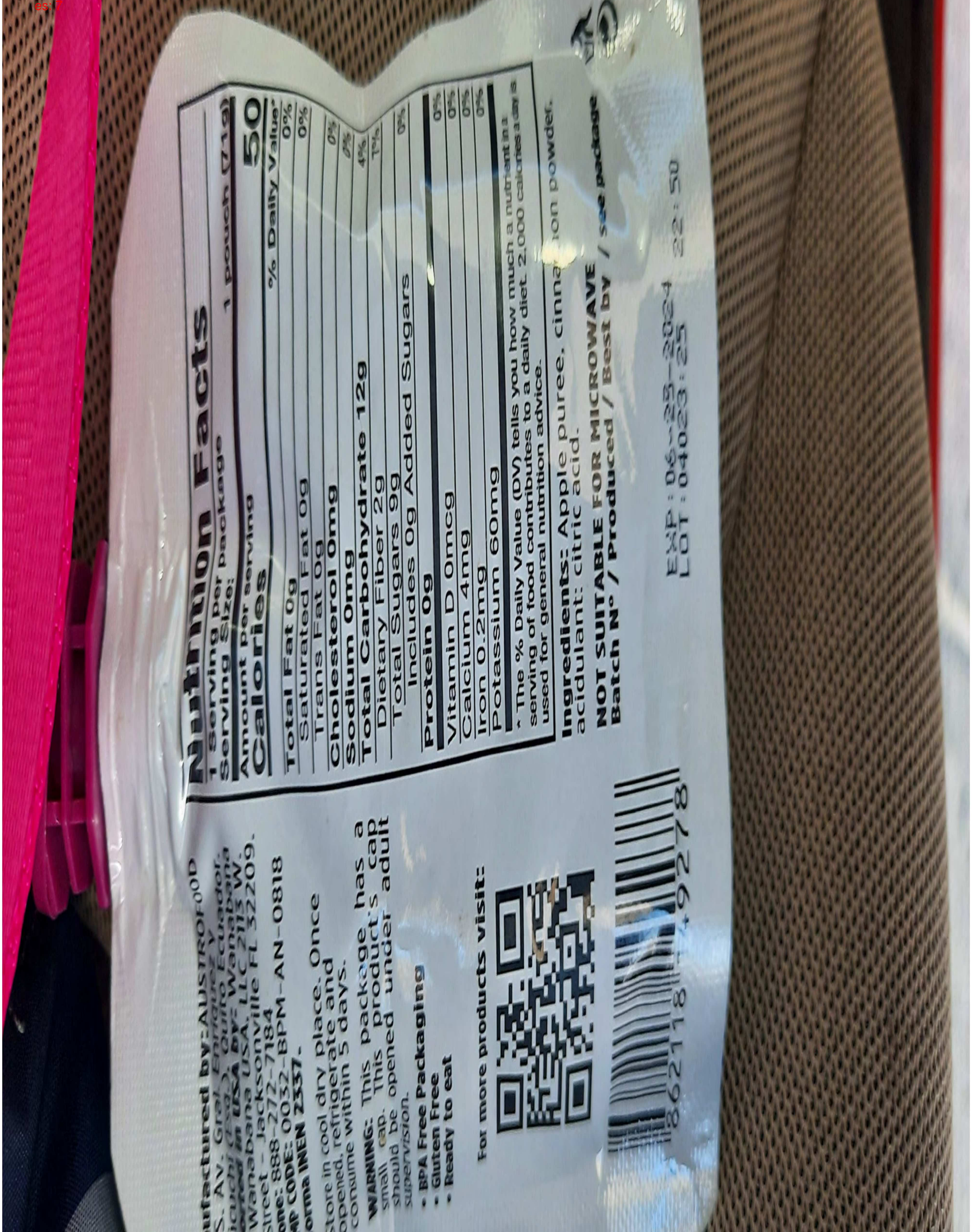
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

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

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

	Telephone number	(b)(6)	
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	03-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

WANA BANA
APPLE
CINNAMON
FRUIT PUREE
#1 IAM FRUIT
NO SUGAR ADDED
KOSHER
Net Weight: 2.50 oz (71g)
Gluten Free
Preservatives


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, cinna ion powder, acidulant: citric acid.
NOT SUITABLE FOR MICROWAVE
Batch N° / Produced / Best by / see package
EXP: 06-25-2024 22:50
LOT: 04023:25
ufactured by:AUSTROFOOD
S. Av. Gral. Enriquez y
Quito Ecuador.
in USA by: Wanabana
Wanabana USA, LLC 2113 W.
Street - Jacksonville FL 32209.
one: 888-272-7184
MP CODE: 0032-BPM-AN-0818
orma INEN 2337.
Store in cool dry place. Once opened, refrigerate and consume within 5 days.
WARNING: This package has a small cap. This product's cap should be opened under adult supervision.
• BPA Free Packaging
• Gluten Free
• Ready to eat
For more products visit:
862118 49278

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	02-Nov-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

My daughter was a consumer of WanaBana Apple-Cinnamon fruit pouches over the past year, upon seeing the recall notice I got her bloodwork tested last week and immediately threw out all pouches. Her lead level was 16.9, and the (b)(6) DOH is aware as well. https://www.fda.gov/food/outbreaks-foodborne-illne ss/investigation-elevated-lead-levels-applesauce-p ouches-november-2023

Relevant Test/Laboratory Data 1 of 1

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

	More Information Available?	

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

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

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

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

	Snack

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	
	Date of Birth	(b)(6)
	Weight	11.25 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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

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

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

List all current prescription medications and medical devices being used.

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

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

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

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

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	06-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	11-Oct-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

I'm reporting a high lead level for my son, (b)(6), after consuming Wanna Banana pouches. During a routine well-child exam on 10/11/23 my son recieved a finger-stick blood test that resulted in a value of 5.1. He had received a lead test the year prior that resulted in a normal range value. So this was a new diagnosis. Subsequently, we returned to the pediatrician on 10/12/23 and a venous blood draw was completed. His result was 4.3 ug/dL. We followed the pediatricians recommendations closely. We have a newer home and all toys are new as well. We keep our home clean and there are no hobby materials that could contain lead in the home. This was a mystery to us until the recent announcement regarding lead in Wanna Banana. He had actually consumed 3 packets the week prior to his testing. We have removed the remaining packets and he has not eaten any since the announcement. I also want to mention that we live in (b)(6) and travel often to (b)(6). It's possible that the packets were purchased at a (b)(6) Dollar Tree.

Relevant Test/Laboratory Data 1 of 2

	Test Name	BLOOD-STICK TO CHECK LEAD LEVELS	Test Date	11-Oct-2023	
	Test Result	5.1	Test Unit		
	Low Test Range	0	High Test Range	3.5	
	More Information Available?				

Relevant Test/Laboratory Data 2 of 2

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

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

	Did the problem return if the person started taking or using the product again?				

Drug Therapy 1 of 1

	Expiration date	18-Apr-2024			
	Lot number	Unable to read			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				

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

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	11.25 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Global Development Delays, Suspected Early Autism

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

Amoxicillin

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

My son was born Preterm at 29 weeks. He is also a twin. His twin brother tested in normal ranges for lead, but did not consume as much of the Wanna Banana products as his brother.

List all current prescription medications and medical devices being used.

Albuterol nebulizer, Triamcinolone- both PRN

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

Pediasure

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

Primary?	Yes
Reporter is Patient?	

	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(b)(6)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b)(6)	
	Telephone number		
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	06-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Nov-2023	CTU Received Date	06-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	31-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

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

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD, BLOOD (PEDS) VENOUS	Test Date	31-Oct-2023	
Test Result	4.2 high	Test Unit	GRAMS PER DECILITER	
Low Test Range	0	High Test Range	3.4	

	More Information Available?	

Additional Comments

Pediatric lead test on my son shows high level of lead.

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date			
	Lot number			
	Dosage Form			
	Quantity	Other	If Other	2 Ounce(s)
	Frequency	Other	If Other	Eat two
	How was it taken or used	Oral	If Other	
	Date the person first started taking or using the product	26-Oct-2023		
	Date the person stopped taking or using the product	27-Oct-2023		

Date the person reduced dose of the product	27-Oct-2023	
Give best estimate of duration		
Is therapy still on-going?		

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

It was a snack

Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(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	16.2 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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

None

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

None

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

None

List all current prescription medications and medical devices being used.

None

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

None

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

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

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	06-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-Nov-2023	CTU Received Date	07-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☑ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	05-Jul-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

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

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

Relevant Test/Laboratory Data 1 of 3

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

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

Relevant Test/Laboratory Data 2 of 3

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

Relevant Test/Laboratory Data 3 of 3

	Test Name	VENOUS BLOOD DRAW LEAD TEST	Test Date	05-Oct-2023	
	Test Result	8.8	Test Unit	MICROGRAMS PER DECILITRE	
	Low Test Range	0	High Test Range	5	
	More Information Available?				

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes	
Did the problem return if the person started taking or using the product again?	Doesn't Apply	

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	01-Feb-2023		
Date the person stopped taking or using the product	29-Jul-2023		
Date the person reduced dose of the product	29-Jul-2023		
Give best estimate of duration			
Is therapy still on-going?			

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

Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

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

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

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

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

List all current prescription medications and medical devices being used.

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

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

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b)(6)
Middle Name	
First name	(b)(6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b)(6)
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	07-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-Nov-2023	CTU Received Date	07-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	07-Nov-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

https://www.fda.gov/food/outbreaks-foodborne-illne ss/investigation-elevated-lead-levels-applesauce-p ouches-november-2023#contact Our 18 month old son ate quite a few of these and has lead levels of 4.8. We just wanted to report this as recommended. It was the WanaBana apple cinnamon pouches. We threw out any we had of the brand just in case.

Relevant Test/Laboratory Data 1 of 1

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

	More Information Available?	

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

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

	Date the person reduced dose of the product	
	Give best estimate of duration	3 Month
	Is therapy still on-going?	

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

	Food

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b)(6)
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Age (specify unit of time for age)	18 Month(s)
	Date of Birth	
	Weight	9.9 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

☑ White ☐ Black or African American	

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

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

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

List all current prescription medications and medical devices being used.

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

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

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

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	07-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Nov-2023	CTU Received Date	08-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

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

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	28-Oct-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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

My infant consumed 2 pouches of wanabana apple cinnamon and now has a lead level of 13ug/dL. Child appears healthy at this time. Pouches were eaten on October 37 and 28. Test was run Oct 31, results received that Friday. As of Nov 3rd pouches were still being sold. When I told the manager, they removed them from shelves but said there had been no message from corporate (dollar tree) Lot:10022 19 19

Relevant Test/Laboratory Data 1 of 1

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

	More Information Available?	

Additional Comments

Section B - Product Availability

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

Section C - About the Products 1 of 1

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

Drug Therapy 1 of 1

	Expiration date	31-Dec-2023		
	Lot number	10022 19 19		
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used		If Other	
	Date the person first started taking or using the product	27-Oct-2023		
	Date the person stopped taking or using the product	28-Oct-2023		

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

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

Food

Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b)(6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	7 Month(s)
Date of Birth	
Weight	8.775 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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

None

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

None

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

List all current prescription medications and medical devices being used.

None

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

None

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

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

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	08-Nov-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

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

NING: This package has a
sm cap. This product's cap
sho be opened under adult
supision.

- Free Packaging
- Gluten Free
- Ready to eat

For more products visit:

7 862118 149278

Nutrition Facts

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

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

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: Apple puree, cinnamon powder, acidulant: citric acid.

NOT SUITABLE FOR MICROWAVE
Batch N° / Produced / Best by / see package

EXP: 12- 2023
LOT: 1002 [illegible]. 19