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)		

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-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)

My son used to eat the Wana Bana fruit pouches, which came out today as being recalled for lead. After his 2 year well visit, his blood levels tested elevated for lead. For months we could not figure out the cause. My local county health department came and inspected my home and did not find anything. I did give them a sample of this fruit pouch and they said they could not test it. I believe the lead is present in other flavors, please test them. Once my son stopped eating them, his levels went from 8.6 to 1.9. I am hoping it does not cause long term damage for him.

Relevant Test/Laboratory Data 1 of 2

Test Name	LEAD, BLOOD	Test Date	16-Jun-2023
Test Result	8.6	Test Unit	MICROGRAMS PER MILLILITRE
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	LEAD, BLOOD	Test Date	28-Sep-2023	
Test Result	1.9	Test Unit	MICROGRAMS PER DECILITRE	
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

This was after we stopped giving him the Wana Bana fruit 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 fruit pouches		
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?	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-Aug-2022			
Date the person stopped taking or using the product	01-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

Toddler 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)	2 Year(s)
Date of Birth	

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		
	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):	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	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	30-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 son ingested lead contaminated apple sauce.

Relevant Test/Laboratory Data 1 of 1

	Test Name	PEDS LEAD	Test Date	30-Oct-2023
	Test Result	6.7	Test Unit	MICROGRAMS PER DECILITRE

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)	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)	Wana bana		
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?	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	17-Mar-2024		
Lot number	01023:17		
Dosage Form			
Quantity		If Other	
Frequency	Daily	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	01-Jul-2023		

	Date the person stopped taking or using the product	25-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)	
	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.

Cefdinir

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	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	

REPORT INFORMATION

Report Profile

Report Version	FPSR.FDA.DSR.M.V1
Report Category	Mandatory Dietary Supplements Report
Submitted	2023-11-01 19:24:16 EST
FDA ICSR ID	2147728
Submitted by	francisco@wanabanafruits.com

Report Identifying Information

Please enter a title to help you identify this report. Consider using your firm's internal case tracking number for simplified recordkeeping	Wanabana Apple cinnamon pouch 2.5 oz
What type of report are you submitting?	Serious adverse event and Product Problem (e.g., defects that may have caused or contributed to a serious adverse event)
Enter the date you received the initial report:	10/27/2023
How did the initial reporter learn of the serious adverse event or product problem? (check all that apply)	Other
If other, please describe	Contacted by the FDA by telephone
Regulatory Status	Mandatory

Contact Information - Manufacturer, Packer, or Distributor Site Information

My account address is the same as the manufacturer, packer, or distributor address	Yes
Organization name	Austrofood S.A.S.
Organization type	Manufacturer
Food facility registration number	14992177026
Country	ECUADOR
Street address line 1	Ave. General Enriquez
Street address line 2	Lote 8 y Tanicuchi
City/Town	Sangolqui
State	<blank>
State/Province	Pichincha
Mail/ZIP Code	<blank>
Postal Code	170501
I am the point of contact for the facility listed above	Yes
First name	Francisco
Last name	Pena
Job title	CEO
Email	francisco@wanabanafruits.com
Confirm email	francisco@wanabanafruits.com
Primary phone	593991036405
Other phone	14073776796
Fax	<blank>

Contact Information- Report Submitter

Contact Information - Initial Reporter

Did the initial reporter indicate that they also reported the event to the FDA?	Unknown
Does the initial reporter wish to remain anonymous to the FDA?	No

Salutation	<blank>
First name	<blank>
Last name	<blank>
Email	<blank>
Confirm email	<blank>
Phone	<blank>
Country	<blank>
Street address line 1	<blank>
Street address line 2	<blank>
City/Town	<blank>
State	<blank>
Mail/ZIP code	<blank>
Was the initial reporter a healthcare professional?	Unknown

Relevant Details

Patient identifier	(b)(6)
Gender	<blank>
Age at time of event, if unknown, please enter Date of birth below	<blank>
Select unit of measure	<blank>
Date of birth	<blank>
Weight	<blank>
Select unit of measure	<blank>
Height	<blank>
Select unit of measure	<blank>

Problem Details

Outcomes attributed to adverse event (check all that apply)	Other serious (important medical events)
If other, please describe	Test result showed elevated concentrations of lead
Date of death	<blank>
Please describe the event or problem	Test result showed elevated concentrations of lead.
Date of event	10/27/2023
Duration of adverse event	1

Select unit of measure	day
Please provide relevant medical history, including pre-existing conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) :	<blank>
Do you have any relevant tests/laboratory data information to report?	No

Adverse Event Terms

Relevant Tests/Laboratory Data

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Wanabana Apple cinnamon fruit puree 2.5 oz x 3 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	2.5
Select unit of measure	oz
Barcode identifier	7862118149278
Select identifier type	Other
If other, please describe	Pack X3 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	11022:11
Expiration/use-by date	01/10/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	12/09/2022
End:	10/28/2023
Duration of product use	14

Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	2.5
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	Not Applicable
Did the event reoccur when product use resumed?	Not Applicable
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Apple puree
If other, please describe	Apple puree
Ingredient amount	70.87
Select unit of measure	g

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.09
Select unit of measure	g

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.04
Select unit of measure	g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz X 4 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011555
Select identifier type	Other
If other, please describe	Pack x4 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Apple
If other, please describe	Apple

Ingredient amount	70.60
Select unit of measure	g

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Weis cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041497216123
Select identifier type	Other
If other, please describe	Pack x 20 units

Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:28
Expiration/use-by date	07/28/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz X 12 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011524
Select identifier type	Other
If other, please describe	Pack x 12 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023

Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank>
Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz X 20 units
Product manufacturer, packer or distributor	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011579
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Producto ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Did the event stop when product use stopped or amount consumed was reduced?	<blank>

Did the event reoccur when product use resumed?	<blank>
Please provide any notes describing the product's usage.	<blank>

Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Product Relevant Details

I have reviewed the ingredients listed for	

each product, if available, and made any necessary corrections	Yes

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Apple Cinnamon Fruit Puree 2.5oz x 3 unit
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	2.5
Select unit of measure	oz
Barcode identifier	782118149278
Select identifier type	Other
If other, please describe	Pack x 3 units
Diagnosis or reason for use (indication):	<blank>
Lot number	11022:10
Expiration/use-by date	01/10/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	12/09/2022
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	week(s)
Amount consumed per serving	2.5
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	<blank>

Concomitant Ingredient Details

Ingredient name	Apple puree

If other, please describe	Apple puree
Ingredient amount	70.87
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.09
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.04
Select unit of measure	g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz x 4 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011555
Select identifier type	Other
If other, please describe	Pack x 4 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	<blank>

Concomitant Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	CITRIC ACID
If other, please describe	<blank>
Ingredient amount	0.05
Select unit of measure	g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Weis cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041497216123
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:28
Expiration/use-by date	07/28/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	<blank>

Concomitant Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz x 12 units

Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011524
Select identifier type	Other
If other, please describe	Pack x 12 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	<blank>

Concomitant Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate

If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Concomitant Product Information

Select full name of product as it appears on the package label	Other
Full name of product as it appears on the package label	Schnucks cinnamon applesauce 3.2oz x 20 units
Product manufacturer, packer, distributor or other responsible party	Austrofood S.A.S.
Product strength	3.2
Select unit of measure	oz
Barcode identifier	041318011579
Select identifier type	Other
If other, please describe	Pack x 20 units
Diagnosis or reason for use (indication):	Product ready to eat
Lot number	05023:19
Expiration/use-by date	07/19/2024

Concomitant Product Use Details

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:	<blank>
End:	10/28/2023
Duration of product use	14
Select unit of measure	month(s)
Frequency of consumption/use	1
Select unit of measure	day(s)
Amount consumed per serving	3.2
Select unit of measure	oz
Administration route	oral
Please provide any notes describing the product's usage:	Prodcut ready to eat

Concomitant Ingredient Details

Ingredient name	Apple
If other, please describe	Apple
Ingredient amount	70.60
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Apple puree concentrate
If other, please describe	Apple puree concentrate
Ingredient amount	18.90
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	Cinnamon powder
If other, please describe	Cinnamon powder
Ingredient amount	0.45
Select unit of measure	g

Concomitant Ingredient Details

Ingredient name	CITRIC ACID
Ingredient amount	0.05
Select unit of measure	g

Concomitant Product Relevant Details

I have reviewed the ingredients listed for each product, if available, and made any necessary corrections	Yes

HL7 Batch Information

HL7 Batch Control Information

Submitting Organization Id	SRPCIT

HL7 Batch Sender Information

Sender Id	SRPCIT
Job Title	Mandatory Dietary Supplement Submitter
Phone	593991036405
Email	francisco@wanabanafruits.com

HL7 Batch Receiver Information

Batch Receiver (Root)	USFDA
Batch Receiver (Extension)	US Food and Drug Administration

HL7 Message Information

HL7 Message Control Information

Unique Sender Identifier SRPCIT

Profile Identifier FPSR.FDA.DSR.M.V1.ACCOUNT.AEPP

HL7 Message Sender Information

Unique Sender Identifier ID-14992177026

Organization Name Austrofood S.A.S.

Title Mandatory Dietary Supplement Submitter

HL7 Message Receiver Information

Message Receiver Id USFDA

Attached Files

None

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	02-Nov-2023	CTU Received Date	02-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	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 son has a lead level of 28.8 micrograms per deciliter after eating WanaBana puree packs. We're in (b)(6) He's getting a venous blood test tomorrow to confirm the level.

Relevant Test/Laboratory Data 1 of 1

Test Name	BLOOD TEST (CAPILLARY)	Test Date	01-Nov-2023
Test Result	28.8	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?	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	
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		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	6 Month
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

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)	1 Year(s)
Date of Birth	
Weight	10.35 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	02-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	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	30-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)

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)

The wanabana brand fruit purée pouches were recalled so I had my daughters blood lead level tested and it came back 15.5 mcg/dl, she began becoming extremely fussy, irritable, sleeping less and loss of appetite.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD (VENOUS)	Test Date	30-Oct-2023
Test Result	15.5	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)	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?	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	31-Mar-2024	
Lot number	01023311205	
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	20-Sep-2023	
Date the person stopped taking or using the product	30-Oct-2023	

Date the person reduced dose of the product	30-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

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	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	
Date of Birth	(b)(6)
Weight	10.35 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	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):	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	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)	

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)

We were made aware of a recall for Wanabana fruit pouches as they contained high levels of lead. Our daughter consumed these pouches so we called our pediatric office and they recommended that our daughter get a blood draw to check her lead levels. We had her tested and received the news that she had high levels of lead, though not high enough that it needed immediate medical attention. We were advised to check her blood again in 6 months.

Relevant Test/Laboratory Data 1 of 1

Test Name	BLOOD TEST FOR LEAD	Test Date	31-Oct-2023
Test Result	5	Test Unit	MICROGRAMS PER DECILITRE
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?	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			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wana Bana Apple Cinnamon Fruit Puree		
Name of the company that makes (or compounds) the product	Wana Bana		
Product Type(check all that apply)	☑ 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		If Other	
Frequency	As needed	If Other	
How was it taken or used	Oral	If Other	
Date the person first started taking or using the product	01-Jul-2022		
Date the person stopped taking or using the product	01-Nov-2023		
Date the person reduced dose of the product			

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

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

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	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)

N/A

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

N/A

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

N/A

List all current prescription medications and medical devices being used.

None

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

Vitamin D

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	(b)(6)
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):	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	06-Jun-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☑ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

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

My child tested positive for high levels of lead in his blood after having a baseline of no lead 6 months prior. We had our house, his daycare, and family members houses tested including the soil and water with no answer. He eats "wanna banana" pouches regularly. With the new recall we believe that is how he obtained lead posioning.

Relevant Test/Laboratory Data 1 of 1

Test Name	LEAD	Test Date	06-Jun-2023
Test Result	11	Test Unit	
Low Test Range	0	High Test Range	