CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag

Low Test Range

More Information Available?

	sic Deta	ile	1011 00.	time zone			
			CDI	R-CTU	Orial	nating Account	FAERS
Company Unit			O (Drug)		nating Account ce Form Type	E2B XML 3500B	
Source Medium Priority		Rou	` -/	Source	се гопп туре	EZB XIVIL 3300B	
		uto Calculation Rule		une			
			No	2-4 2022	CTU	Descrived Data	20.04.2022
	DA Receiv		30-0	Oct-2023		Received Date	30-Oct-2023
	ΓU Triage					Data Entry Date	
	eport Type	9	-	ntaneous	Repo	rt Classification	Drug
	ssign To		Use	r 			
	ser/Group						
Fc	rward to	Department					
Ca	ase Priorit	ty	Dire	ct			
	ntact						
	ase eporter	First Name		Last Name		Email Address	Phone
<u> </u>		(b)(6)		b)(6)			
			\				
Se		About the Problem					
		nd of problem was it? all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)				
	(011001()	an triat apply)	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				
		problem occurred	16-Jun-2023				
	Serious		No				
	-	of the following happen? all that apply)		Hospitalization - admitted or sta	ayed Ion	ger	
	(Oncor a	an triat apply)	<u>∠</u> F	Required help to prevent perma	anent ha	rm	
			닏	Disability or health problem			
			ᄖ	Birth defect			
			닏	ife-threatening			
				Death			
4 7	س عدر الح	hat hannened and how		Other serious/important medica		nt(Please Describe Below) / details as possible FDA	may reach out to you for
an	y ad <u>diti</u> o	nal documents if nece	ssary	y)	ппапту		
						ay as being recalled for lead.	
						ire out the cause. My local co m a sample of this fruit pouch	
						m. Once my son stopped eati	
	from 8.6 to 1.9. I am hoping it does not cause long term damage for him.						
Re	levant T	est/Laboratory Data	<u> </u>			1	1 of 2
	Test Na	me	LEA	D, BLOOD	Test	Date	16-Jun-2023
	Test Res	sult	8.6		Test	Unit	MICROGRAMS PER MIL LILITRE
\neg			1				

Generated by: SYSTEM Generated on: 30-Oct-2023 14:47:50 Page 1 of 5

High Test Range

CTU_No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 5

Re	levant Test/Laboratory Data			2 of 2	
	Test Name	LEAD, BLOOD	Test Date	28-Sep-2023	
	Test Result	1.9	Test Unit	MICROGRAMS PER DEC	
	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
	This was after we stopped giving l	nim the Wana Bana fruit pouc	ches		
Se	ction 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			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	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 of Generic Biosimilar	or an Outsourcing Facility		
	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			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form		1		
	Quantity		If Other		

Generated by: SYSTEM Generated on: 30-Oct-2023 14:47:50 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag

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	of			
Give best estimate of duration				
Is therapy still on-going?				
Why was the person using the	product? (such as what o	condition was it suppose	d to treat) 1 of 1	
Toddler snack				
Returned to Manufacturer On				
Section D - About the Medical I	Device			
Name of medical device				
Name of the company that makes the medical device				
Other identifying information (T locate them)	he model, catalog, lot, se	erial, or UDI number, and	the expiration date, if you can	
Model Number				
Catalog Number				
Lot Number				
Serial Number				
UDDI Number				
Expiration date				
Was someone operating the medical device when the proble occurred?	m			
For implanted medical devices	ONLY (such as pacemal	kers, breast implants, etc	C.)	
Date the implant was put in		Date the implant was tal relevant)	ken out (If	
Section E - About the Person V	/ho 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)			

Generated by: SYSTEM Generated on: 30-Oct-2023 14:47:50 Page 3 of 5

Date of Birth

CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag

	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	
Lis	t known medical conditions (S	such as diabetes, high blood pressure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	bass het all allergies (saeit as t	o drage, recae, penetral enteriors	
l ic	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
		ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
LIS	at all current prescription medic	cations and medical devices being used.	
Lis	t all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
S-0	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
		(b)(6)	
	Middle Name	(b)(6)	
		(b)(6)	
	First name	(b)(6)	
	Number/Street		
	City		
	State/Province		1 1

Generated by: SYSTEM Generated on: 30-Oct-2023 14:47:50 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-80094 | Department: CFSAN | RCT No.: RCT-1175983 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 5

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	

Generated by: SYSTEM Generated on: 30-Oct-2023 14:47:50 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag

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

My son ingested lead contaminated apple sauce.

Basic Detai	İs					
Company Unit		CDER-CTU	Originating Account	FAERS		
Source Med	ium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
Override Au	to Calculation Rule	No				
FDA Receive	ed 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 D	Department					
Case Priority	у	Direct		_		
Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b)(6)	(b)(6)	(b)(6)	(b)(6)		
Section A -	About the Problem					
	d of problem was it? Ill 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				
Date the	problem occurred	Had problems after switching from one product maker to another maker 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)					
	· · ·	wit hannoned (Include o	es many dotaile as nossible.	EDA may reach out to you for		
		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)				

Relevant Test/Laboratory Data		1 of 1

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

Generated by: SYSTEM Generated on: 30-Oct-2023 17:17:59 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag

		~
- 65		n
00	•	~

	Low Test Range	0	High Test Range	3.5	
	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the product? (check yes if you are	Yes			
	including a picture)				
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	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 of Generic Biosimilar	or an Outsourcing Facility		
	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			
Dr	ug 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	01-Jul-2023	J		

Generated by: SYSTEM Generated on: 30-Oct-2023 17:17:59 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag

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 p	roduct? (such as what condition was it supposed to treat) 1 of 1
Food	
Returned to Manufacturer On	
Section D - About the Medical De	evice
Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The locate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can
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 C	DNLY (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 Wh	no 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

Generated by: SYSTEM Generated on: 30-Oct-2023 17:17:59 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag Asian 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.

Se	ection F - About the Person Fill	ng Out This Form	1 of 1
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	b)(6)	
	Middle Name		
	First name	(b)(6)	
	Number/Street	(0)(0)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(h)(G)	
	Telephone number	(b)(6)	
	Email address		

Generated by: SYSTEM Generated on: 30-Oct-2023 17:17:59 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-80149 | Department: CFSAN | RCT No.: RCT-1176109 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 6

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	

Generated by: SYSTEM Generated on: 30-Oct-2023 17:17:59 Page 5 of 5



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

10/27/2023

report:

How did the initial reporter learn of the serious adverse event or product Other

problem? (check all that apply)

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 Yes address

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

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?

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?

Relevant Details

Patient identifier (b)(6)

Gender <blank>

Age at time of event, <i>if unknown, please enter Date of birth below</i>

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 No report?

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

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 12/09/2022 estimate duration of use below. Start:

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 Not Applicable

reduced?

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

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:

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

reduced?

Did the event reoccur when product use

resumed?

<blank>

Please provide any notes describing the

product's usage.

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:

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
 <blank>

reduced?

Did the event reoccur when product use

esume

Please provide any notes describing the

product's usage.

<blank>

<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
Other

on the package label

Schnucks cinnamon applesauce 3.2oz X 12 units

package label

Full name of product as it appears on the

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:

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 <blank>

reduced?

<blank>

Did the event reoccur when product use

esume

Please provide any notes describing the

product's usage.

colonies

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:

estimate duration of use below. Start:

End: 10/28/2023

<blank>

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

reduced?

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

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

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

12/09/2022

estimate duration of use below. Start:

End: 10/28/2023

Duration of product use 14

Select unit of measure month(s)

Frequency of consumption/use

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
Other

on the package label

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 of

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:

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:

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

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 <blank>

estimate duration of use below. Start:

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

Othe

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

estimate duration of use below. Start:

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

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.

Other

Product strength 3.2

Select unit of measure of

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:

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 Yes necessary corrections

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

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag

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	1100-010@ida.iiiis.gov) (L2D)		
-	I			
Contact				
Case First Name	Last Name	Email Address	Phone	
Reporter	(1.)(0)			
(b)(6)	(b)(6)	(b)(6)	(b)(6)	
Section A - About the Problem				
What kind of problem was it?	Were burt or had a had side	e effect (including new or worsening symptom	(ec	
(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?	Hospitalization - admitted or stayed longer			
(Check all that apply)	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 howard and howard and and itional documents if neces		as many details as possible FD	A may reach out to you for	
My son has a lead level of 28.8 m getting a venous blood test tomor		r eating WanaBana puree packs. W	/e're in (b)(6) He's	

Re	elevant Test/Laboratory Data	1 of 1		
	Test Name	BLOOD TEST (CAPILLAR Y)	Test Date	01-Nov-2023
	Test Result	28.8	Test Unit	MICROGRAMS PER DEC ILITRE
	Low Test Range	0	High Test Range	3.4

Generated by: SYSTEM Generated on: 02-Nov-2023 21:47:50 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag

es: 5

	More Information Available?						
Ac	Additional Comments						
Se	ection 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					
Se	ection C - About the Products			1 of 1			
	Suspect	Yes					
	Primary?	Yes					
	Туре	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 Cinnamo	on				
	Name of the company that makes (or compounds) the product						
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar	or an Outsourcing Facility				
	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					
Dr	ug 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						

Generated by: SYSTEM Generated on: 02-Nov-2023 21:47:50 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag

	Date the person reduced dose of the product					
	Give best estimate of duration	6 Month				
	Is therapy still on-going?	Yes				
W			ch as what co	ndition was it supposed to treat)	1 of 1	
	The first person doing the product. (cool do mat condition was it supposed to troat)					
	Returned to Manufacturer On					<u></u>
Se	ection D - About the Medical De	evice				
	Name of medical device					
	Name of the company that					
O#	makes the medical device	madal aa	talaa lat aari	ol or IDI number and the eveire	ation data if you can	
loc	ate them)	e model, ca	italog, lot, sen	al, or UDI number, and the expira	illon date, ii you can	
						П
	Model Number					
	Catalog Number					
	Lot Number					
	Serial Number					
	UDDI Number					
	Expiration date					
	Was someone operating the					
	medical device when the problem occurred?					
Εo	r implanted medical devices C	NI V (such	as nacemake	rs hreast implants etc.)		
_	ate the implant was put in	TILL (SUCI	аз расстакс	Date the implant was taken out (If		
	ate the miplant has parm			relevant)		
Se	ction E - About the Person Wh	no Had the l	Problem			
	Person's Initials	(b)(6)				Т
	Sex	Male				
	Gender	Cisgender r	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 Hispan	ic/Latino			
	Race (Check all that apply)	American	Indian or Alaska Na	tive		
		Native Hawaiian or Other Pacific Islander				
		Asian				

Generated by: SYSTEM Generated on: 02-Nov-2023 21:47:50 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag

es: 5

	White Black or African American	
Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as to drugs, foods, pollen or others)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medications and medical devices being used.	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.	
Se	ection F - About the Person Filling Out This Form 1 of 1	
	Primary? Yes	T
	Reporter is Patient?	
	Title	
	Last name (b)(6)	
	Middle Name	
	First name (b)(6)	
	Number/Street (b)(6)	
	Oily	
	State/Province	
	Country UNITED STATES	
	ZIP or Postal code Telephone number	-
	ZIP or Postal code Telephone number Email address (b)(6)	

Generated by: SYSTEM Generated on: 02-Nov-2023 21:47:50 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81237 | Department: CFSAN | RCT No.: RCT-1177213 | CTU Triage Date: 03-Nov-2023 | Total Pag

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	

Generated by: SYSTEM Generated on: 02-Nov-2023 21:47:50 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag

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

Basic Details	asic Details							
Company Unit	CDER-CTU	CDER-CTU Originating Account						
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							
-								

Co	ontact						
1	fase First Name Reporter	Last Name	Email Address	Phone			
<u>_</u>	a (b)(6)	(b)(6)	(b)(6)	(b)(6)			
Se	ection A - About the Problem						
	What kind of problem was it? (Check all that apply)	Used a product incorrectly Noticed a problem with the	de effect (including new or worsening symptor which could have or led to a problem e quality of the product				
	Date the problem occurred	30-Oct-2023					
	Serious	Yes					
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted Required help to prevent p Disability or health probler Birth defect Life-threatening Death Other serious/important m	permanent harm				
4. ar	Tell us what happened and howny additional documents if nece	v it happened (Include ssary)	e as many details as possible F	DA may reach out to you for			
	The wanabana brand fruit purée p mcg/dl, she began becoming extre		I had my daughters blood lead leve eping less and loss of appetite.	I tested and it came back 15.5			

R€	elevant Test/Laboratory Data	1 of 1		
	Test Name LEAD (VENOUS)		Test Date	30-Oct-2023
	Test Result	15.5	Test Unit	MICROGRAMS PER DEC
	Low Test Range		High Test Range	

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:05 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag

	More Information Available?				
Ad	lditional Comments				
Se	ection 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			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes		_	
	Туре	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 of Generic Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generic		
	Strength		If Other		
	NDC number			J	
	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			
Dr	ug 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			

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:05 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 6

	Date the person reduced dose of the product	30-Oct-2023				
	Give best estimate of duration					1
	Is therapy still on-going?					
W		oduct? (such as v	what cor	ndition was it supposed to treat)	1 of 1	
•	To eat	oddor. (oddir do r	Wildt 001	idition was it supposed to treaty	1 01 1	Т
	10 000					
	Returned to Manufacturer On					
S-0	ction D - About the Medical De	aviac.				
36	Name of medical device	evice				
	Name of the company that					
	makes the medical device					
Otl	ner identifying information (The	e model, catalog,	lot, seria	al, or UDI number, and the expira	ation date, if you can	
IOC	ate them)					
						<u> </u>
	Model Number					-
	Catalog Number					
	Lot Number					<u> </u>
	Serial Number					<u> </u>
	UDDI Number					
	Expiration date					
	Was someone operating the					
	medical device when the problem occurred?					
Εn	r implanted medical devices O	NI Y (such as nac	remakei	rs hreast implants etc.)		
_	ate the implant was put in	1421 (30011 03 par	Jemakei	Date the implant was taken out (If		
				relevant)		
Se	ction E - About the Person Wh	no Had the Proble	m			
	Person's Initials	(b)(6)				
	Sex	Female				
	Gender	Cisgender woman	/girl			
	Please Specify Other Gender					
	Age (specify unit of time for age)					\vdash
	Date of Birth	(b)(6)				
	Weight	10.35 kg				\vdash
	Ethnicity (Choose only one)	Not Hispanic/Latin	0			
	Race (Check all that apply)					
	~ ~ (~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	American Indian or Native Hawaiian or				
		Asian	Other Pacif	ic isialidel		

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:05 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag

	White Black or African American	
Lis	st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Ρle	ease list all allergies (such as to drugs, foods, pollen or others)	
Lis	st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medications and medical devices being used.	
Lis	st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used	d.
Se	ection F - About the Person Filling Out This Form 1 of 1	
	Primary? Yes	
	Reporter is Patient?	
	Title (L.) (C.)	
	Last name (b)(6)	
	Middle Name	
	First name (b) (6)	
	First name Number/Street (b)(6)	
		_
	State/Province Country UNITED STATES	_
	·	
	ZIP or Postal code Telephone number Email address	+
	Email address	

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:05 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81588 | Department: CFSAN | RCT No.: RCT-1177498 | CTU Triage Date: 06-Nov-2023 | Total Pag

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	

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:05 Page 5 of 5



CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 5

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

More Information Available?

Ba	sic Deta	ils							
Co	mpany U	nit	CDI	ER-CTU	Origi	nating Account	FAERS		
Sc	ource Med	lium	MWO (Drug)		Source Form Type		E2B XML 3500B		
Priority			Routine						
Override Auto Calculation Rule			No	No					
FE	A Receiv	ed Date	03-l	Nov-2023	CTU	Received Date	03-Nov-2023		
CTU Triage Date				CTU	Data Entry Date				
Re	eport Type	9	Spc	ntaneous	Repo	rt Classification	Drug		
As	sign To		Use	r					
Us	ser/Group								
Fc	rward to I	Department	∇	CDER (CDER-OSE-RS	SS-CT	J@fda.hhs.gov) (E2B)			
Ca	ase Priorit	у	Dire						
Со	ntact								
	ase	First Name		Last Name		Email Address	Phone		
	eporter	(b)(6)		(b)(6)		b)(6)			
\mathbf{V}					\	D)(O)			
Se		About the Problem							
		nd of problem was it? all that apply)		Were hurt or had a bad side ef	fect (incl	uding new or worsening symptoms)			
	(CHECK &	ali tilat apply)		Used a product incorrectly which	ch 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?			Hospitalization - admitted or stayed longer						
	(Check all that apply)			Required help to prevent permanent harm					
			Disability or health problem						
			Birth defect						
			Life-threatening						
			Death						
1 7	- ,,		Other serious/important medical incident(Please Describe Below) ow it happened (Include as many details as possible FDA may reach out to you for						
4. I an	ell us w v additio	hat happened and hov nal documents if nece	v it h ssar	appened (Include as y)	many	details as possible FDA	may reach out to you for		
	,				s thev	contained high levels of lead.	Our daughter consumed		
	these po	uches so we called our p	ediatı	ric office and they recom	mend	ed that our daughter get a bloo	od draw to check her lead		
		Ve had her tested and rec te medical attention. We				vels of lead, though not high e	enough that it needed		
	mmodia	to modical attention. We	W 010	davised to eneck flor six	ou ug	an in o montho.			
Re	levant T	est/Laboratory Data					1 of 1		
	Test Nar	me	BLC	OOD TEST FOR LEAD	Test	Date	31-Oct-2023		
	Test Res	sult	5		Test	Unit	MICROGRAMS PER DEC		
			_		. 551		ILITRE		
	Low Tes	t Range	0		High	Test Range	3.5		

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:03 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag

	65. 0						
Ac	Iditional Comments	_	_				
Se	ection B - Product Availability						
	Do you still have the product in case we need to evaluate it?	No					
	Do you have a picture of the	No					
	product? (check yes if you are including a picture)						
C c	ection C - About the Products			1 of 1			
JOE	Suspect	Yes		1011			
	Primary?	Yes	_				
	-						
	Type	Drug/Biologic					
	This report is about	Waran Baran Arrala Giranara	F				
	Name of the product as it appears on the box, bottle,	Wana Bana Apple Cinnam	ion Fruit Puree				
	or package (Include as many	pr package (Include as many					
	names as you see) Name of the company that	Wana Bana	Wana Bana				
	makes (or compounds) the	VValla Dalla					
	product						
	Product Type(check all that apply)	Over-the-Counter					
	αρριγ)	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	No					
	stopped taking or using the						
	product?						
	Did the problem return if the person started taking or using the	Doesn't Apply					
	product again?						
Dr	ug 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					

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:03 Page 2 of 5

Date the person reduced dose of

the product

CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pages: 5

	Give best estimate of duration		
	Is therapy still on-going?		
W	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Food		
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
		e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	cate them)		
	Model Number		_
	Catalog Number Lot Number		
_	Serial Number		_
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem		
	occurred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh		
	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	
i		L. I. Haok or African American	

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:03 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pages: 5

LIS	si known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
	N/A		
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	N/A		
Lis	st any other important informati	on about the person (such as smoking, pregnancy, alcohol use, etc.)	
	N/A		
Lis		ations and medical devices being used.	
	None		
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
	Vitamin D		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	b)(6)	
	Middle Name		
	First name	(h)(G)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	b)(6)	
	Telephone number		
		b)(6)	\vdash
	Fax		\vdash
	Reporter Organization		\vdash
l	reporter organization		

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:03 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81560 | Department: CFSAN | RCT No.: RCT-1177403 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 5

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

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:03 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-81881 | Department: CFSAN | RCT No.: RCT-1177845 | CTU Triage Date: 07-Nov-2023 | Total Pag

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		<u>,</u>		
User/Group					
Forward to Department					
Case Priority	Direct				

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
Ø	(b)(6)	(b)(6)	(b)(6)	(b)(6)		
Section A -	- About the Problem					
	nd of problem was it? all that apply)	Used a product incorrectly when the quality of the problem with the quality of the problem.	effect (including new or worsening symnich could have or led to a problem uality of the product			
Date the	problem occurred	06-Jun-2023				
Serious		Yes				
1 1	of the following happen? all that apply)	Hospitalization - admitted or s Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important medi	, ,			
	erious/important medical (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)						
house, h	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		

Generated by: SYSTEM Generated on: 06-Nov-2023 16:15:43 Page 1 of 5