CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag

es: 7

incident(Please Describe Below)

All dates display	ed in the report are in EST(G	MT-05	:00) time zone					
Basic Deta	ils							
Company Unit			ER-CTU	Origin	ginating Account		FAERS	
Source Medium			O (Drug)	Source	ce Form Type		E2B XML 3500	В
Priority		Rou	tine					
Override Au	to Calculation Rule	No						
FDA Receiv	ed Date	30-0	Oct-2023	CTU	Received Date		30-Oct-2023	
CTU Triage	Date			CTU	Data Entry Date			
Report Type	)	Spo	ntaneous	Repo	rt Classification		Drug	
Assign To		Use	r			•		
User/Group								
Forward to I	Department	$\overline{Z}$						
Case Priorit	у	Dire	ect					
Contact								
Case	First Name		Last Name		Email Address		Phone	
Reporter	(b)(6)		(b)(6)		(b)(6)	(b)(6)		
			(2)(3)				(8)(0)	
Section A -	About the Problem							
	d of problem was it?	Were hurt or had a bad side effect (including new or worsening symptoms)						
(Check a	all that 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						
Date the	problem occurred	22-Aug-2023						
Serious		Yes	Yes					
	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					
				nedical incider	nt(Please Describe Relow)			
Othor so	Other serious/important medical incident(Please Describe Below)							

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

My son ate Apple Cinnamon WanaBana fruit puree pouches as a regular part of his diet (4-6 pouches a day) from May 2023 through August 2023. He had his blood lead levels tested on 8/22/2023 as part of a routine screening for daycare and they came back as 19.8ug/dL. The pediatrician, (b)(6)

Health department were working to identify the source of exposure, but home studies, dust wipes, and the XRF gun did not detect a source of exposure for my son in our home. Additionally, my husband and I hired an independent company to perform a separate study that yielded no source of lead exposure in the home. Daycare was also deemed to be an unlikely source of exposure as none of the other children at my son's licensed daycare had elevated lead levels on their tests. Since my son's diagnosis, we have been following the EPA's lead poisoning healthy diet, and in doing so, have eliminated the WanaBana apple cinnamon fruit puree pouches from his diet. His blood lead levels test was repeated on 9/1/2023, 9/14/2023, 9/26/2023, and 10/25/2023. The results were 22.5ug/dL, 22.4ug/dL, 14.3ug/dL, and 9.6ug/dL respectively. My son is currently in treatment at (b)(6)

as a result of this lead exposure. His levels are trending down, but we are extremely concerned about future developmental delays and behavioral issues resulting from this exposure.

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 1 of 6

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag

es: 7

elevant Test/Laboratory Data			1 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	22-Aug-2023
Test Result	19.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available?			
elevant Test/Laboratory Data			2 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	01-Sep-2023
Test Result	22.5	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available?			
elevant Test/Laboratory Data			3 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	14-Sep-2023
Test Result	22.4	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available?			
elevant Test/Laboratory Data			4 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	26-Sep-2023
Test Result	14.3	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available?			
levant Test/Laboratory Data			5 of 5
Test Name	LEAD LEVEL, BLOOD (PE DIATRIC)	Test Date	25-Oct-2023
Test Result	9.6	Test Unit	MICROGRAMS PER DEC
Low Test Range	0	High Test Range	3.4
More Information Available?			
Iditional Comments			
ection B - Product Availability			
Do you still have the product in	Yes		

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 2 of 6

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag

es: 7

	Do you have a picture of the product? (check yes if you are including a picture)	Yes						
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)	WanaBana Apple Cinnamo	n Fuit Puree "I Am Fruit"					
	Name of the company that makes (or compounds) the product	WanaBana LLC, AUSTROF	FOOD					
	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							
	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	Doesn't Apply						
	product again?							
Dr				1 of 1				
Dr	product again?	31-Dec-2023		1 of 1				
Dr	product again? ug Therapy	31-Dec-2023 10022:31 08:10		1 of 1				
Dr	product again? ug Therapy Expiration date			1 of 1				
Dru	product again? ug Therapy Expiration date Lot number		If Other	1 of 1				
Dru	product again?  ug Therapy  Expiration date  Lot number  Dosage Form	10022:31 08:10	If Other If Other					
Dru	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity	10022:31 08:10 Other		2.5 Ounce(s)				
Dru	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency	10022:31 08:10  Other  Other	If Other	2.5 Ounce(s)				
Dru	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started	10022:31 08:10  Other  Other  Oral	If Other	2.5 Ounce(s)				
Dr	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking	10022:31 08:10  Other  Other  Oral  01-May-2023	If Other	2.5 Ounce(s)				
Dr	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  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	10022:31 08:10  Other  Other  Oral  01-May-2023	If Other	2.5 Ounce(s)				
	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Date the person reduced dose of the product  Give best estimate of duration  Is therapy still on-going?	10022:31 08:10  Other  Other  Oral  01-May-2023  31-Aug-2023	If Other  If Other	2.5 Ounce(s) 4-6 pouches/day				
	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Date the person reduced dose of the product  Give best estimate of duration  Is therapy still on-going?	Other Other Oral 01-May-2023 31-Aug-2023 oduct? (such as what con	If Other  If Other	2.5 Ounce(s) 4-6 pouches/day				
	product again?  ug Therapy  Expiration date  Lot number  Dosage Form  Quantity  Frequency  How was it taken or used  Date the person first started taking or using the product  Date the person stopped taking or using the product  Date the person reduced dose of the product  Give best estimate of duration  Is therapy still on-going?	Other Other Oral 01-May-2023 31-Aug-2023 oduct? (such as what con	If Other  If Other	2.5 Ounce(s) 4-6 pouches/day				

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 3 of 6

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag

es: 7

Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot loc	her identifying information (The cate 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?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	o Had the Problem	
	Person's Initials	(b)(6)	
	Sex	Male	_
	Gender	Cisgender man/boy	_
	Please Specify Other Gender		_
	Age (specify unit of time for age)		_
	Date of Birth	(b)(6)	_
	Weight	11.61 kg	_
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
	Elevated Blood Lead Level		
	agen liet all allorgine (euch ag t		

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 4 of 6

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pages: 7

	es: /		
	N/a		
Li	st any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
	N/A		
Li	st all current prescription medi	cations and medical devices being used.	
	N/A		
Li	st all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
	Poly-Vi-Sol		
	1		
S	ection F - About the Person Fil	ling Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
	City		

Fax

Reporter Organization

Department

Reporter Speciality

Today's date

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

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 5 of 6

**UNITED STATES** 

State/Province

ZIP or Postal code
Telephone number
Email address

Country

CTU No.: FDA-CDER-CTU-2023-79839 | Department: CFSAN | RCT No.: RCT-1175836 | CTU Triage Date: 30-Oct-2023 | Total Pag

es:

manufacturer, please mark this box (Confidentiality Requested):

Generated by: SYSTEM Generated on: 30-Oct-2023 09:47:07 Page 6 of 6



CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag

All dates display	ved in the report are in EST(G	MT-05	:00) time zone					
Basic Detai	ils							
Company Unit		CDER-CTU		Origi	Originating Account		FAERS	
Source Med	ium	MW	O (Drug)	Sour	ce Form Type		E2B XML 3500B	
Priority		Rou	tine					
Override Au	to Calculation Rule	No						
FDA Receiv	ed Date	30-0	Oct-2023	CTU	Received Date		30-Oct-2023	
CTU Triage	Date			CTU	Data Entry Date			
Report Type	;	Spo	ntaneous	Repo	ort Classification		Drug	
Assign To		Use	r	'		'		
User/Group								
Forward to [	Department	abla						
Case Priority	у	Dire						
<u> </u>								
Contact			_				_	
Case	First Name		Last Name		Email Address		Phone	
Reporter								
$\square$	(b)(6)		(b)(6)		(b)(6)		(b)(6)	
					( ) ( )			
	About the Problem							
	d of problem was it? all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)						
(Oncor e	iii triat appry)		Jsed a product incorrec	tly which could	have or led to a problem			
			Noticed a problem with	the quality of th	ne product			
			Had problems after swit	ching from one	e product maker to another mal	ker		
Date the	problem occurred	09-0	Oct-2023					
Serious		No						
	of the following happen?		Hospitalization - admitte	ed or stayed lor	nger			
(Спеск а	all that apply)	Required help to prevent permanent harm						
		Disability or health problem						
		Birth defect						
		Life-threatening						
		Death						
			Other serious/important	medical incide	ent(Please Describe Below)			
	nat happened and how nal documents if nece			de as man	y details as possible	FDA ma	y reach out to you t	for
	was one year old 10/7/23							
	y. On 10/9/23 we had his							
	sed by breast milk) turned aw This recall Our pcp wa							<b>y</b>
						,	-	
Relevant To	est/Laboratory Data						1 of 1	

Relevant Test/Laboratory Data						
Test Name	IRON	Test Date	09-Oct-2023			
Test Result	Low (don't remember exac t number)	Test Unit				
Low Test Range		High Test Range				

Generated by: SYSTEM Generated on: 30-Oct-2023 22:17:54 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 7

	More Information Available?						
Ad	ditional Comments						
	PCP is (b)(6)						
Se	ction 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	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)	WanaBana apple puree pou	uches				
	Name of the company that makes (or compounds) the product	WanaBana apple puree pouches					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy 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	21-Sep-2024					
	Lot number	07023211542					
	Dosage Form						
	Quantity		If Other				
	Frequency		If Other				
	How was it taken or used		If Other				
	Date the person first started taking or using the product	01-Aug-2023					
	Date the person stopped taking or using the product	30-Oct-2023					

Generated by: SYSTEM Generated on: 30-Oct-2023 22:17:54 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 7

	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				_
Wł	ny was the person using the pr	oduct? (such as what con	dition was it supposed to trea	t) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Otl	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the exp	iration 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?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b)(6)			
	Sex	Male			
	Gender	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)	1 Year(s)			
	Date of Birth	_			_
	Weight	12.6 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nativ			
		Asian			

Generated by: SYSTEM Generated on: 30-Oct-2023 22:17:54 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pages: 7

		White Black or African American	
Lis	t known medical conditions (	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	None		
Ple	ease list all allergies (such as	to drugs, foods, pollen or others)	
	None		
Lis		tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
	None		
Lis		cations and medical devices being used.	
	None		
Lis	t all over-the-counter medica	tions and any vitamins, minerals, supplements, and herbal remedies being used.	
	None		
<b>S</b> A	ction F - About the Person Fi	lling Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
	State/Province	UNITED STATES	
	ZIP or Postal code		
	Telephone number	(b)(6)	-
	Email address		

Generated by: SYSTEM Generated on: 30-Oct-2023 22:17:54 Page 4 of 5

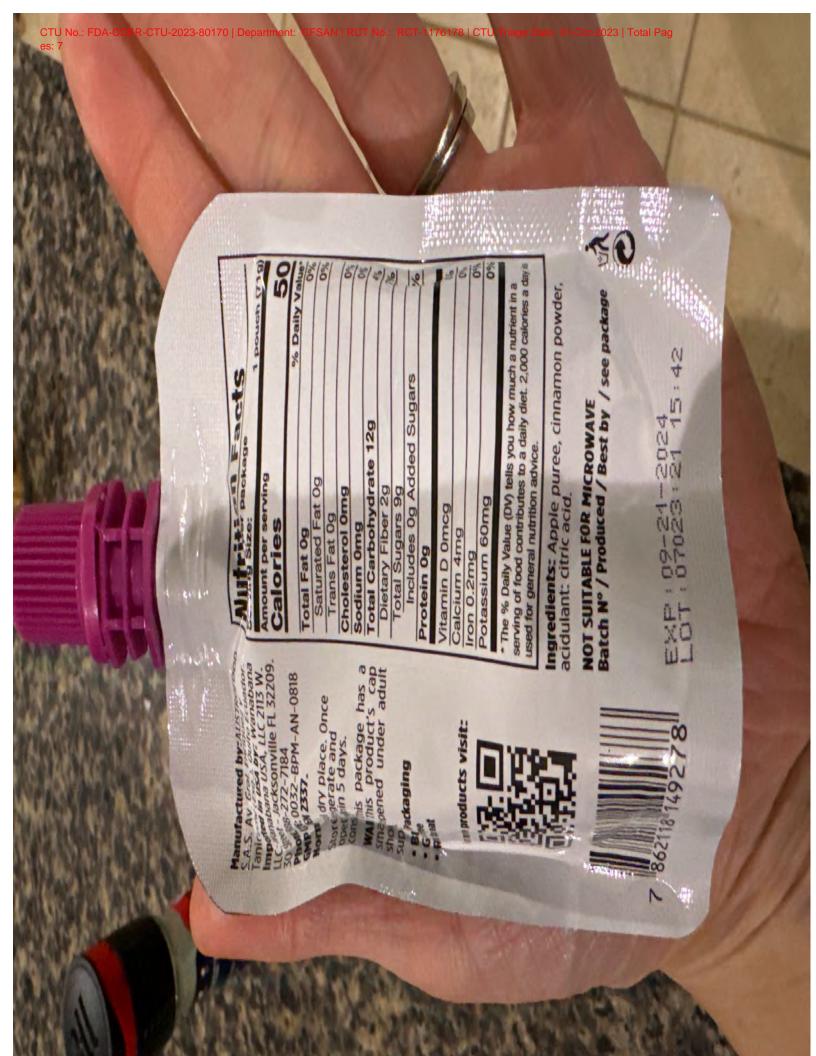
CTU No.: FDA-CDER-CTU-2023-80170 | Department: CFSAN | RCT No.: RCT-1176178 | CTU Triage Date: 31-Oct-2023 | Total Pag

es: 7

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 22:17:54 Page 5 of 5





CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag

Test Name

All dates displ	ayed in the report are in EST(G	MT-05:00) time	zone				
Basic Det	ails						
Company	Unit	CDER-CTU	J	Originating Account		FAERS	
Source Me	edium	MWO (Drug	g)	Source Form Type	,	E2B XML 3500B	
Priority		Routine			1		
Override A	auto Calculation Rule	No					
FDA Rece	ived Date	01-Nov-202	23	CTU Received Dat	te	01-Nov-2023	
CTU Triag	e Date			CTU Data Entry Da	ate		
Report Typ	ре	Spontaneo	us	Report Classification	on	Drug	
Assign To		User					
User/Grou	р						
Forward to	Department	CDER	CDER-OSE-R	SS-CTU@fda.hhs.gc	 ov) (E2B)		
Case Prior	ity	Direct	. (022.1002.11	<u></u>	,,, (===)		
Contact							
Case	First Name	Last N	Name	Email Addre	ess	Phone	
Reporter	(b)(6)	(b)(6)		(h)(c)		/b\/C\	
М	(b)(6)	(b)(0)		(b)(6)		(b)(6)	
Section A	- About the Problem						
	ind of problem was it? all that apply)	Used a pr		ffect (including new or wor ich could have or led to a p ality of the product			
				from one product maker to	another maker		
	e problem occurred	20-Jun-202	<u>23                                    </u>				
Serious		No					
(Check	y of the following happen? 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)					
	what happened and horonal documents if nece		led (Include as	s many details as <sub>l</sub>	possible FDA ma	ay reach out to you for	
Our daughter born on 5/14/2022 had a regular primary care appointment on 6/1/2023 and had the scheduled lead test through finger prick that came back as a 14 lead count, after they found those numbers we were asked to get a blood draw to get a more accurate number that will be shown below in relevant tests. The blood drawn test came back with still raised lead levels and we had the (b)(6) Health Department come out to do a check and they couldn't find anything that they didn't think raised concerns for lead. After that meeting with the health department they asked us to do another blood draw 3 months later that came back higher than the first blood draw, so she was still being exposed with no answers. After trying to get the health department to come back out to do another check, they didn't think it was necessary to check our homes, toys, or any of her food. After a month of trying to get the health department to come back out, the FDA released that the Wanabana Purée pouches had been recalled due to high lead content and our daughter had been consuming those over the last 9 months averaging 4-6 a week.							
Relevant	Test/Laboratory Data					1 of 2	
recvant	root/Laboratory Data						

Test Result	7.1 mcg/dL	Test Unit		

Test Date

20-Jun-2023

Generated by: SYSTEM Generated on: 01-Nov-2023 21:17:50 Page 1 of 5

LEAD BLOOD TEST

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag

es: 7

	Low Test Range	< 3.5	High Test Range		
	More Information Available?			J	
Re	elevant Test/Laboratory Data			2 of 2	
	Test Name	LEAD BLOOD TEST	Test Date	11-Sep-2023	
	Test Result	8.5 mcg/dL	Test Unit		
	Low Test Range	< 3.5	High Test Range		
	More Information Available?			J	
Ad	ditional Comments				
S 0	ction B - Product Availability				
Se	•				
	Do you still have the product in case we need to evaluate it?	Yes			ı
	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)	Wanabana purée pouch			
	Name of the company that makes (or compounds) the product				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy 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?				
	Did the problem return if the person started taking or using the product again?				
Dr	ug Therapy			1 of 1	
	Expiration date				_
	Lot number			·	

Generated by: SYSTEM Generated on: 01-Nov-2023 21:17:50 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag

es: 7

	Dosage Form				
	Quantity		If Other		
	Frequency	Twice a day	If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of the product				
	Give best estimate of duration	7 Month			
	Is therapy still on-going?				
Wł	ny was the person using the pr	oduct? (such as what	condition was it supposed to	o treat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
	ner identifying information (The ate them)	e model, catalog, lot, s	serial, or UDI number, and th	e expiration date, if you can	1
	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 pacema	akers, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken relevant)	out (If	
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b)(6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender	-			

Generated by: SYSTEM Generated on: 01-Nov-2023 21:17:50 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag

es: 7

	Age (specify unit of time for age)		
	Date of Birth	(b)(6)	
	Weight	11.7 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
	N/A		
Ple	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	st all current prescription medic	cations and medical devices being used.	
	N/A		
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
	N/A		
Se	ection F - About the Person Filli	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(b)(6)	
	Number/Street	(b)(6)	

Generated by: SYSTEM Generated on: 01-Nov-2023 21:17:50 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-80914 | Department: CFSAN | RCT No.: RCT-1176847 | CTU Triage Date: 02-Nov-2023 | Total Pag

es: 7

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

Generated by: SYSTEM Generated on: 01-Nov-2023 21:17:50 Page 5 of 5





CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 4

All c	dates display	red in the report are in EST(G	MT-05	:00) time zone					
Ва	isic Deta	ils							
C	ompany U	nit	CDI	ER-CTU	Orig	inating Account	F	AERS	
So	ource Med	ium	MW	/O (Drug)	Soui	ce Form Type	E	E2B XML 3500	
Pı	riority		Rou	ıtine					
0	verride Au	to Calculation Rule	No						
FI	DA Receiv	ed Date	03-1	Nov-2023	CTU	Received Date	0	3-Nov-2023	
C.	TU Triage	Date			CTU	Data Entry Date			
R	eport Type	)	Spc	ntaneous	Rep	ort Classification	Г	Drug	
As	ssign To		Use	er					
U:	ser/Group								
Fo	orward to I	Department		CDER (CDER-OSE-RS	SS-CT	TIMfda hhs gov) (E2B)			
C	ase Priorit	V	Dire		30-01	Owida.iiii3.gov) (LZD)			
		•							
Сс	ontact								
C	ase eporter	First Name		Last Name		Email Address		Phone	
V		(b)(6)		(b)(6)		(b)(6)		(b)(6)	
Α	PATIFN	T INFORMATION							
	ſ	dentifier (In Confidence)	(b)(6)			<u> </u>			T
	Age		17 [	Month(s)					
	Date of E	 Birth							
	Sex		Fen	 nale					
	Gender			cline to answer					
		Specify Other Gender			_				
	Weight	poonly earler contact	9 kg	1	_				
		(Check single best	-	Hispanic/Latino					
	answer)			·					
	Race (Cl	neck all that apply)		Asian					
			<u> </u>	American Indian or Alaska Nat	tive				
				Black or African American					
			<del>     </del>	White					
			<u> </u>	Native Hawaiian or Other Pacit	fic Islan	der			
В.	ADVERS	SE EVENT, PRODUC	T PF	ROBLEM					
		Report (check all that		Adverse Event					
	apply)			Product Use/Medication Error					
				Product Problem (e.g., defects	/malfun	ctions)			
	_		+	Problem with Different Manufa	cturer o	f Same Medicine			
	Serious		Yes	<b>.</b>					
		Attributed to Adverse heck all that apply)		Death					
	Lveiii (C	πουκ απ ιπαι αρριγ)		Life Threatening					
				Hospitalization (initial or prolon	nged)				
			Y	Other Serious or Important Me	dical Ev	vents			
			الــا∖	Disability or Permanent Damad	ae				

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:07 Page 1 of 4

CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag

	4
es:	4

I					1
		Congenital Anomaly/Birth			
Date of Death	<b>1</b>	Required Intervention to P	Prevent Permanent Impairment/Da	amage	
Date of Event		01-Nov-2023			
Date of this R		03-Nov-2023			
Describe Eve		uct Use Error: was eating	WanaBana fruit pouches. e screening 5/16/23 was <		
Relevant Test/L	aboratory Data				1 of 1
Test Name		LEAD VENOUS	Test Date	01-	-Nov-2023
Test Result		10.8	Test Unit		CROGRAMS PER DEC
Low Test Ran	nge		High Test Range		
More Informa	tion Available?				
Additional Com	ments				
		g Preexisting Medical (	Conditions		
C. PRODUCT A					
	able for Evaluation? product to FDA)	No			
Returned to N	/lanufacturer on				
	a picture of the eck yes if you are cture)	No			
D. PRODUCT(S	3)				1 of 1
Suspect		Yes			
Primary?		Yes			
Туре		Drug/Biologic			
This report in	volves:	Food/Medical food			
Name,Strength	,Manufacturer/Co	mpounder (from produ	ıct label)		
Product Name	e	WanaBana fruit pouch			
Strength			If Other		
Manufacturer	/Compounder				

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:07 Page 2 of 4

CTU No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 4

	NDC# or Unique ID				
	Product Type(check all that apply)	OTC Compounded Generic Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?	Yes			
	Event Reappeared after	Doesn't Apply			
Dr	Reintroduction ? ug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced		_		
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				
Dia	agnosis for Use (indication)			1 of 1	
F	SUSPECT MEDICAL DEVICE				
<u> </u>	Brand Name	·			
	Common Device Name				
	Procode				
		1			
	Manufacturer Name				
	Manufacturer Name City				
	Manufacturer Name City State				
	City				
	City State				
	City State Model #				
	City State Model # Lot #				
	City State Model # Lot # Catalog #				
	City State Model # Lot # Catalog # Expiration Date				
	City State Model # Lot # Catalog # Expiration Date Serial #	Health Professional Patient/Consumer Other			
	City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)#	Patient/Consumer			

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:07 Page 3 of 4

CTU\_No.: FDA-CDER-CTU-2023-81562 | Department: CFSAN | RCT No.: RCT-1177405 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 4

disclosed to the manufacturer

	If Explanted, Give Date					
	Is this a single-use device that was reprocessed and reused on a patient?					
	If Yes for the above field, Enter Name and Address of Reprocessor					
	Was this device serviced by a third party?					
F.	OTHER (CONCOMITANT) ME	EDICAL PRODUCTS				
	CONCOMITANT MEDICAL PROD					
G.	REPORTER				1 of 1	
	Primary?	Yes				
	Reporter is Patient?					
	Title			_		
	Last Name	(b)(6)		_		
	Middle Name			_		
	First Name	(b)(6)				
	Address	(b)(6)				
	City	(D)(D)		_		
	State/Province/Region					
	Country	UNITED STATES	If Other			
	ZIP/Postal Code	/h\/6\				
	Phone	(b)(6)				
	Email					
	Fax					
	Reporter Organization					
	Department					
	Reporter Speciality					
	Health Professional?	Yes				
	Occupation	Physician	If Other			
	Also Reported to	Manufacturer/Comp User Facility Distributor/Importer	ounder			
	If you do NOT want your identity	Yes				

Generated by: SYSTEM Generated on: 03-Nov-2023 15:18:07 Page 4 of 4

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag

All c	lates display	red in the report are in EST(G	MT-05	:00) time zone					
Ва	sic Detai	ls							
C	ompany U	nit	CDE	ER-CTU	Origir	ating Account	!	FAERS	
So	ource Med	ium	MW	O (Drug)	Sourc	e Form Type	!	E2B XML 3500B	
Pı	riority		Rou	tine					
O	verride Au	to Calculation Rule	No						
F	DA Receiv	ed Date	03-1	Nov-2023	CTU	Received Date	(	04-Nov-2023	
CTU Triage Date  Report Type				CTU	Data Entry Date				
R	eport Type	:	Spo	ntaneous	Repo	t Classification	1	Drug	
As	ssign To		Use	r					
U	ser/Group								
Fo	orward to [	Department	$oldsymbol{ abla}$	CDER (CDER-OSE-F	RSS-CTU	J@fda.hhs.gov) (E2B)			
C	ase Priorit	<i>y</i>	Dire			<u> </u>			
Сс	ntact								
l .	ase eporter	First Name		Last Name		Email Address		Phone	
V		(b)(6)		(b)(6)		(b)(6)		(b)(6)	
Se	ction A -	About the Problem							
	(Check a	d of problem was it? Il that apply)		Used a product incorrectly wondered a problem with the quadrant problems after switching	hich could				
	Date the	problem occurred	24-0	Oct-2023					
	Serious		No						
Did any of the following happen? (Check all that apply)  Required help to preve Disability or health prot Birth defect Life-threatening Death				.ife-threatening Death Other serious/important med	rmanent ha	rm t(Please Describe Below)			
		nat happened and how nal documents if nece			as many	details as possible F	DA may	y reach out to you fo	or
	his baby an 5am weekend over the When I r WanaBa office an levels. I I above ra	1st time purchase of Wasitter reported to me that comiting. I called my sons for signs of dehydration, weekend. He was seen a eturned home I laid my sona apple cinnamon pouch waited for a response. I waited for a response. I had previous doctor orderinge. His pediatrician just curring symptoms since. I	he did s pedi if no it her on do nes. I n the rs fror recor	dn't have much of an a atrician to make an ap improvement by Mono pediatricians office Mown for a nap. After doi mmediately I called his meantime I took my sons 1 year well mmended retesting in a	appetite a appointment day they appenday Oc ing so I g s doctor I son to the ness visi January.	Il day. The following mont. They advised me to would see him in clinic. It 30 where he was diagot online and saw a new pack to report my concelab at the hospital to hat. I received his results to My sons symptoms did	orning 10/2 watch my He had vo nosed wit vs article a rn. I left a ave bloodv oday and resolve o	26/23 my son woke up son closely over the omiting and diarrhea th the stomach flu. about an Urget recall for message with the from work done for his lead hid lead levels were on Wednesday 11/1/23	or nt

R	elevant Test/Laboratory Data			1 of 1
	Test Name	LEAD LEVEL BLOODWO	Test Date	30-Oct-2023

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:32 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 7

	Test Result	4.2	Test Unit	GRAMS PER LITRE	
	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
, (0					
					_
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	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	WanaBana Cinnamon apple	esauce pouch		_
	appears on the box, bottle, or package (Include as many names as you see)				
	Name of the company that makes (or compounds) the product	WanaBana			
	Product Type(check all that	Over-the-Counter			_
	apply)	Compounded by a Pharmacy of	or an Outsourcing Facility		
		Generic			
		Biosimilar			
	Strength		If Other		_
	NDC number				_
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?				_
Dr	ug Therapy			1 of 1	
	Expiration date	25-Jun-2024			=
	Lot number	04023 25			_
	Dosage Form				_
	Quantity		If Other		_
	Frequency		If Other		_
	How was it taken or used		If Other		

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:32 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 7

	Date the person first started taking or using the product	24-Oct-2023			
	Date the person stopped taking or using the product	24-Oct-2023			
	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				
WI	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to to	reat) 1 of 1	
	Returned to Manufacturer On			-	_
Se	ection D - About the Medical De	evice			
	Name of medical device	74100			
	Name of the company that			_	
	makes the medical device				
	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the o	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?				
Fο	r implanted medical devices O	NI Y (such as nacemake	rs breast implants etc.)		_
	ate the implant was put in	TTET (Such as passinate)	Date the implant was taken ou	ut (If	
			relevant)		
Se	ection E - About the Person Wh	o Had the Problem			
	Person's Initials	(b)(6)			
	Sex	Male		-	_
	Gender	Cisgender man/boy			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b)(6)			
	Weight	9.9 kg			
	Ethnicity (Choose only one)	Hispanic/Latino		-	_

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:32 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 7

	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
l ic	st known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
	N/A	don as diasetes, high shood pressure, earner, flear disease, or ethers)	
	1477		
DI	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	NKDA	o drugs, roods, polieri or otriers)	
	NINDA		
LIS	st any other important informati	on about the person (such as smoking, pregnancy, alcohol use, etc.)	1
Lis	st all current prescription medic	cations and medical devices being used.	
Lis	st all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used	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		
	_	(h)(6)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	ZII UI I USIAI UUU <del>U</del>	(b)(6)	

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:32 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81594 | Department: CFSAN | RCT No.: RCT-1177506 | CTU Triage Date: 06-Nov-2023 | Total Pag

es: 7

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

Generated by: SYSTEM Generated on: 04-Nov-2023 08:41:32 Page 5 of 5





CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag

Test Result

All dates displ	ayed in the report are in EST(G	MT-05	i:00) time zone				
Basic Det	ails						
Company	Unit	CDI	ER-CTU	Origir	ating Account	FAERS	
Source Me	edium	MW	/O (Drug)	Sourc	e Form Type	E2B XML 3500B	
Priority		Rou	utine			,	
Override A	Auto Calculation Rule	No					
FDA Rece	ived Date	1-60	Nov-2023	CTU	Received Date	06-Nov-2023	
CTU Triag	e Date			CTU	Data Entry Date		
Report Ty	ре	Spo	ontaneous	Repo	rt Classification	Drug	
Assign To		Use	er				
User/Grou	p						
Forward to	Department	$\nabla$	 ]				
Case Prior	rity	Dire					
	·						
Contact							
Case	First Name		Last Name		Email Address	Phone	
Reporter	/b\/6\		(b)(6)		(b)(C)	(b)(C)	
М	(b)(6)		(0)(0)		(b)(6)	(b)(6)	
Section A	- About the Problem						
Other sinciden  4. Tell us vany additi	y of the following happen? c all that apply)  serious/important medical at(Please Describe Below) what happened and how onal documents if neces ughter was a consumer of Ner bloodwork tested last we	Vanaleek and	Used a product incorrectly which Noticed a problem with the qual Had problems after switching from Nov-2023  Hospitalization - admitted or state Required help to prevent permatorisability or health problem Birth defect  Life-threatening  Death  Other serious/important medicate  Tappened (Include as y)  Bana Apple-Cinnamon from immediately threw out	yed longuenent ha	e product product maker to another maker ger	n seeing the recall notice 9, and the <sup>(5)(6)</sup> DOH is	
	ber-2023					1 of 1	
	Test/Laboratory Data					1 of 1	
Test N	ame	LEA	AD	Test I	Date	02-Nov-2023	

Low Test Range	High Test Range	

Test Unit

Generated by: SYSTEM Generated on: 06-Nov-2023 14:15:26 Page 1 of 5

16.9

CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 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?	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)	WanaBana Apple Cinnamo	n Fruit Puree pouch		
	Name of the company that makes (or compounds) the product	WanaBana			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy 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?				
	Did the problem return if the person started taking or using the product again?				
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 or using the product				

Generated by: SYSTEM Generated on: 06-Nov-2023 14:15:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?				_
Wł	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat	t) 1 of 1	
	Snack				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
		e model, catalog, lot, seria	al, or UDI number, and the exp	iration 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?				
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b)(6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b)(6)			_
	Weight	11.25 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			_
	Race (Check all that apply)	American Indian or Alaska Nati			
		Asian			

Generated by: SYSTEM Generated on: 06-Nov-2023 14:15:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag es: 5

		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	to drugs, foods, pollen or others)	
Lis	t any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medi	ications and medical devices being used.	
Lis		tions and any vitamins, minerals, supplements, and herbal remedies being use	ed.
	Has now started iron supplement	ts to increase speed in which lead will leave the body	
_	"		
Se	ction F - About the Person Fil Primary?	Iling Out This Form 1 of Yes	1
	Reporter is Patient?	165	
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(b)(c)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number	(b)(6)	
	Email address		

Generated by: SYSTEM Generated on: 06-Nov-2023 14:15:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81856 | Department: CFSAN | RCT No.: RCT-1177770 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

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

Generated by: SYSTEM Generated on: 06-Nov-2023 14:15:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag

all dates displayed in the report are in EST(GMT-05:00) time zone							
Basic Deta	ils						
Company U	Init	CDER-CTU	Origii	nating Account	FAERS		
Source Med	lium	MWO (Drug)	Source	ce Form Type	E2B XML 3500B		
Priority		Routine					
Override Au	ito Calculation Rule	No					
FDA Received Date		06-Nov-2023	CTU	Received Date	06-Nov-2023		
CTU Triage Date			CTU	CTU Data Entry Date			
Report Type		Spontaneous	Repo	Report Classification Drug			
Assign To		User					
User/Group							
Forward to I	Department						
Case Priorit	у	Direct	Direct				
Contact							
Case Reporter	First Name	Last Na	me	Email Address	Phone		

Contact					
Case	First Name	Last Name	Email Address	Phone	
Reporter					
$\square$	(b)(6)	(b)(6)	(b)(6)	(b)(6)	
			(8)(8)		
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)					

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

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

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

Relevant Test/Laboratory Data

1 of 2

Generated by: SYSTEM 06-Nov-2023 15:15:26 Generated on: Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	Test Name	BLOOD-STICK TO CHEC K LEAD LEVELS	Test Date	11-Oct-2023	
	Test Result	5.1	Test Unit		
	Low Test Range	0	High Test Range	3.5	
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 2	
	Test Name	VENOUS BLOOD-DRAW TO CHECK FOR LEAD LE VELS	Test Date	12-Oct-2023	
	Test Result	4.3	Test Unit		
	Low Test Range	0	High Test Range	3.5	
	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)	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)	Wanna Banana			
	Name of the company that makes (or compounds) the product	Austrofood			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy 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?				

Generated by: SYSTEM Generated on: 06-Nov-2023 15:15:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	Did the problem return if the person started taking or using the product again?			
Dr	ug Therapy			1 of 1
	Expiration date	18-Apr-2024		
	Lot number	Unable to read		
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used	Oral	If Other	
	Date the person first started taking or using the product			
	Date the person stopped taking or using the product			
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?			
W	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to trea	at) 1 of 1
	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			
	her identifying information (The	e model, catalog, lot, seri	al, or UDI number, and the ex	piration 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?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast implants, etc.)	
D	ate the implant was put in		Date the implant was taken out ( relevant)	(If

Generated by: SYSTEM Generated on: 06-Nov-2023 15:15:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

Se	ction E - About the Person Wh	no Had the Problem	
	Person's Initials	(b)(6)	П
	Sex	Male	
	Gender	Cisgender man/boy	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b)(6)	
	Weight	11.25 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American	
Lis	st known medical conditions (S	such as diabetes, high blood pressure, cancer, heart disease, or others)	
	Global Development Delays, Susp	, , , , , , , , , , , , , , , , , , ,	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or others)	
	Amoxicillin		П
Lis	t any other important informati	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
		reeks. He is also a twin. His twin brother tested in normal ranges for lead, but did not	
	consume as much of the Wanna I	Запапа products as his brother.	
Lis	t all current prescription medic	cations and medical devices being used.	
	Albuterol nebulizer, Triamcinolone	e- both PRN	
Lis	t all over-the-counter medicati	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
	Pediasure		
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
			1

Generated by: SYSTEM Generated on: 06-Nov-2023 15:15:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81862 | Department: CFSAN | RCT No.: RCT-1177805 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

Title	
Last name	(b)(6)
Middle Name	
	(1 ) (0)
Number/Street	(b)(6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	(h)(c)
Telephone number	(b)(6)
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	06-Nov-2023
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 06-Nov-2023 15:15:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pag

Test Result

Low Test Range

All d	ates display	ed in the report are in EST(G	MT-05	:00) time zone				
Ва	sic Detai	ls						
Company Unit		CDER-CTU		Origin	nating Account	FAERS		
Sc	ource Med	ium	MW	O (Drug)	Source	ce Form Type	E2B XML 3500B	
Pr	riority		Rou	ıtine				
O۱	verride Au	to Calculation Rule	No					
F	DA Receiv	ed Date	06-1	Nov-2023	CTU	Received Date	06-Nov-2023	
C	TU Triage	Date			CTU	Data Entry Date		
Re	eport Type		Spo	ntaneous	Repo	rt Classification	Drug	
As	sign To		Use	r				
Us	ser/Group							
Fo	rward to [	Department	$\overline{Z}$	1				
Ca	ase Priority	/	Dire	ect				
Со	ntact							
	ase	First Name		Last Name		Email Address	Phone	
	eporter	(1.) (0)		(1.)(0)		(1.)(0)	(1) (2)	
$\overline{\mathbf{A}}$	1	(b)(6)		(b)(6)		(b)(6)	(b)(6)	
0	otion A	About the Problem						
Se		d of problem was it?						
		ll that apply)				uding 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  31-Oct-2023					
	Serious	problem occurred	No No					
		of the following happen?						_
		Il that apply)	Hospitalization - admitted or stayed longer					
			Required help to prevent permanent harm					
			Disability or health problem					
				Birth defect				
			Life-threatening  Death					
				Death Other serious/important medica	ıl incider	nt(Please Describe Below)		
4 7	Tell us wh	nat happened and hov		· · · · · · · · · · · · · · · · · · ·		details as possible FDA	may reach out to you fo	r
an	y additio	nal documents if nece	ssar	у)	many	actaile de peccibie i B/ (	may reach eat to years	
	Child cor	nsumed Wananbana App	le Cir	nnamon pouch and was	blood t	ested. Child has high level of	lead on blood work	
Re	levant Te	est/Laboratory Data					1 of 1	
	Test Nan	ne	LEA NO	AD, BLOOD (PEDS) VE US	Test	Date	31-Oct-2023	

Generated by: SYSTEM 06-Nov-2023 19:45:30 Page 1 of 5 Generated on:

Test Unit

High Test Range

4.2 high

0

**GRAMS PER DECILITER** 

3.4

CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	More Information Available?				
Ad	ditional Comments				
	Pediatric lead test on my son show	ws high level of lead.			
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)	Wanabana Apple Cinnamor	n pouch		
	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	Other	If Other	2 Ounce(s)	_
	Frequency	Other	If Other	Eat two	
	How was it taken or used	Oral	If Other		
	Date the person first started taking or using the product	26-Oct-2023			
	Date the person stopped taking or using the product	27-Oct-2023			

Generated by: SYSTEM Generated on: 06-Nov-2023 19:45:30 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	Date the person reduced dose of the product	27-Oct-2023			
	Give best estimate of duration				_
	Is therapy still on-going?				_
W	ny was the person using the pr	oduct? (such as what cor	idition was it supposed to treat)	1 of 1	
	It was a snack				
	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				_
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if y	ou 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 pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection 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	16.2 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			_
	Race (Check all that apply)	American Indian or Alaska Nati	ve		_
		Native Hawaiian or Other Pacif			
		Asian			

Generated by: SYSTEM Generated on: 06-Nov-2023 19:45:30 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pages: 5

		White Black or African American	
Lic	at known modical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
LIS	None	buch as diabetes, high blood pressure, cancer, heart disease, or others)	
	None		
DI	assa list all allergies (such as t	to drugs, foods, pollen or others)	
1 10	None	to drugs, 100ds, policit of others)	Т
Lis	st any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
	None	3,1 - 3 - 3,1	Π
Lis	st all current prescription medic	cations and medical devices being used.	
	None		
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
	None		
Se	ection F - About the Person Fill	ling Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(c)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(h)(6)	
	Telephone number	(b)(6)	
	Email address		

Generated by: SYSTEM Generated on: 06-Nov-2023 19:45:30 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-81909 | Department: CFSAN | RCT No.: RCT-1177905 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

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

Generated by: SYSTEM Generated on: 06-Nov-2023 19:45:30 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

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

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

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
$\square$	(b)(6)	(b)(6)	(b)(6)	(b)(6)

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

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

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

Re	elevant Test/Laboratory Data			1 of 3
	Test Name	ROUTINE LEAD TEST	Test Date	05-Jul-2023
	Test Result	12.9	Test Unit	MICROGRAMS PER DEC

Generated by: SYSTEM Generated on: 07-Nov-2023 10:45:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	Low Test Range	0	High Test Range	5	
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 3	ı
	Test Name	VENOUS BLOOD DRAW L EAD TEST	Test Date	02-Aug-2023	
	Test Result	13.1	Test Unit	MICROGRAMS PER DEC	
	Low Test Range	0	High Test Range	5	_
	More Information Available?				
Re	levant Test/Laboratory Data			3 of 3	
	Test Name	VENOUS BLOOD DRAW L EAD TEST	Test Date	05-Oct-2023	
	Test Result	8.8	Test Unit	MICROGRAMS PER DEC	
	Low Test Range	0	High Test Range	5	
	More Information Available?				_
Ad	ditional Comments				
Se	ction B - Product Availability				Ī
	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)	WanaBana Apple cinnamon	n 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	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				

Generated by: SYSTEM Generated on: 07-Nov-2023 10:45:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

	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				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	01-Feb-2023			
	Date the person stopped taking or using the product	29-Jul-2023			
	Date the person reduced dose of the product	29-Jul-2023			
	Give best estimate of duration				
	Is therapy still on-going?  ny was the person using the pr			treat) 1 of 1	
					_
	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				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seri	al, 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?				

Generated by: SYSTEM Generated on: 07-Nov-2023 10:45:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction 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				
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nativ  Native Hawaiian or Other Pacifi  Asian  White  Black or African American			
				`	
Lis	t known medical conditions (S	uch as diabetes, high bloc	od pressure, cancer, heart diseas	se, or others)	
					_
PIE	ease list all allergies (such as t	o drugs, foods, pollen or c	others)		
Lis	t any other important informati	on about the person (such	h as smoking, pregnancy, alcoho	l use, etc.)	
Lis	t all current prescription medic	ations and medical device	es being used.		
Lis	t all over-the-counter medicati	ons and any vitamins, mir	nerals, supplements, and herbal i	remedies being used.	

Generated by: SYSTEM Generated on: 07-Nov-2023 10:45:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-82007 | Department: CFSAN | RCT No.: RCT-1177969 | CTU Triage Date: 07-Nov-2023 | Total Pag

es: 5

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

Generated by: SYSTEM Generated on: 07-Nov-2023 10:45:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pag

	ed in the report are in EST(GI	MT-05:00) time zone		
Basic Detai	ls			
Company U	nit	CDER-CTU	Originating Account	FAERS
Source Med	ium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority		Routine		
Override Auto Calculation Rule		No		
FDA Receiv	ed Date	07-Nov-2023	CTU Received Date	07-Nov-2023
CTU Triage	Date		CTU Data Entry Date	
Report Type		Spontaneous	Report Classification	Drug
Assign To		User		,
User/Group				
Forward to D	Department	CDER (CDER-O	OSE-RSS-CTU@fda.hhs.gov) (E2B)	)
Case Priority	/	Direct		
Contact				
Case	First Name	Last Name	Email Address	Phone
Reporter				
	(b)(6)	(b)(6)	(b)(6)	(b)(6)
Section A -	About the Problem			
Date the Serious Did any o	d of problem was it? Il that apply)  problem occurred  of the following happen? Il that apply)	Used a product incorre  Noticed a problem with Had problems after swi 07-Nov-2023  No  Hospitalization - admitt Required help to preve Disability or health prot Birth defect Life-threatening Death	ent permanent harm	
4.Tell us whany addition	nat happened and how nal documents if nece	v it happened (Inclu ssary)	de as many details as possible	FDA may reach out to you for
novembe	er-2023#contact Our 18 m	onth old son ate quite	vestigation-elevated-lead-levels-ap a few of these and has lead levels amon pouches. We threw out any w	of 4.8. We just wanted to report

ĮR€	elevant Test/Laboratory Data			1 of 1
	Test Name	LEAD BLOOD TEST	Test Date	07-Nov-2023
	Test Result	4.8	Test Unit	MICROGRAMS PER DEC
	Low Test Range	<3.5	High Test Range	>3.5

Generated by: SYSTEM Generated on: 07-Nov-2023 18:15:36 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pag

es: 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?	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)	WanaBana apple cinnamon			
	Name of the company that makes (or compounds) the product	WanaBana			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy 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?				
	Did the problem return if the person started taking or using the product again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				

Generated by: SYSTEM Generated on: 07-Nov-2023 18:15:36 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pag

es: 5

	Date the person reduced dose of the product				
	Give best estimate of duration	3 Month			_
	Is therapy still on-going?				_
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat	) 1 of 1	
	Food				_
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the exp	iration 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?				
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection 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)	18 Month(s)			
	Date of Birth				_
	Weight	9.9 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif			
ı					

Generated by: SYSTEM Generated on: 07-Nov-2023 18:15:36 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pages: 5

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

Generated by: SYSTEM Generated on: 07-Nov-2023 18:15:36 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-82283 | Department: CFSAN | RCT No.: RCT-1178197 | CTU Triage Date: 08-Nov-2023 | Total Pag

es: 5

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

Generated by: SYSTEM Generated on: 07-Nov-2023 18:15:36 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pag

All dates display	red in the report are in EST(GI	MT-05	:00) time zone				
Basic Deta	ls						
Company U	nit	CDE	ER-CTU	Orig	nating Account		FAERS
Source Med	ium	MW	O (Drug)	Sou	ce Form Type		E2B XML 3500B
Priority		Rou	tine				
Override Au	to Calculation Rule	No					
FDA Receiv	ed Date	1-80	Nov-2023	CTU	Received Date		08-Nov-2023
CTU Triage	Date			CTU	Data Entry Date		
Report Type	;	Spo	ntaneous	Rep	ort Classification		Drug
Assign To		Use	r				
User/Group							
Forward to I	Department	V		_			
Case Priorit	у	Dire		_			
Contact							
Case	First Name		Last Name		Email Address		Phone
Reporter	/h.\/c\		(1.)(0)		(1 ) (0)	_	(1.)(0)
М	(b)(6)		(b)(6)		(b)(6)		(b)(6)
Section A -	About the Problem					_	
Date the Serious Did any (Check a	d of problem was it? all that apply)  problem occurred  of the following happen? all that apply)  nat happened and how hal documents if nece		Used a product incorrectly who Noticed a problem with the quality and problems after switching Oct-2023  Hospitalization - admitted or sequired help to prevent permonant problem Birth defect after threatening Ocath  Other serious/important medicappened (Include as	ich could cality of the	ne product product maker to another maken to another make	er	y reach out to you for
My infan this time were still	t consumed 2 pouches of Pouches were eaten on being sold. When I told t (dollar tree) Lot:10022 1	wana Octol	abana apple cinnamon ber 37 and 28. Test wa	s run C	Oct 31, results received the	nat Friday	. As of Nov 3rd pouches
Relevant I	est/Laboratory Data						1 of 1
Relevant I	estreaduratury Data						1011

R	elevant Test/Laboratory Data			1 of 1
	Test Name	BLOOD LEAD TEST, VEN	Test Date	31-Oct-2023
	Test Result	13	Test Unit	MICROGRAMS PER DEC
	Low Test Range		High Test Range	

Generated by: SYSTEM Generated on: 08-Nov-2023 13:15:27 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pag

es: 7

	More Information Available?				
Ad	ditional Comments				
Se	ction 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	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)	Wanabana apple cinnamor	n fruit purée		
	Name of the company that makes (or compounds) the product				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		1		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?				
	Did the problem return if the person started taking or using the product again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	31-Dec-2023	_		
	Lot number	10022 19 19			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	27-Oct-2023			
	Date the person stopped taking or using the product	28-Oct-2023			

Generated by: SYSTEM Generated on: 08-Nov-2023 13:15:27 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pag

es: 7

	Date the person reduced dose of the product				
	Give best estimate of duration	_			
	Is therapy still on-going?				
Wł	ny was the person using the pr	oduct? (such as what con	dition was it supposed to treat)	1 of 1	
	Food				
	Returned to Manufacturer On				_
	Neturned to Maridiacturer Off				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot		e model. catalog. lot. seria	I, or UDI number, and the expira	tion date. if vou can	
	ate 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	s. breast implants. etc.)		
	ate the implant was put in	i i	Date the implant was taken out (If		
			relevant)		
Se	ction 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)	7 Month(s)			
	Date of Birth				
	Weight	8.775 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nativ	ve		
		Native Hawaiian or Other Pacific			
		Asian			

Generated by: SYSTEM Generated on: 08-Nov-2023 13:15:27 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pages: 7

		White Black or African American	
ll is	t known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	None	puer de diasetes, mgm bioca pressure, canoer, meart disease, er ethers)	
Ple	ease list all allergies (such as	to drugs, foods, pollen or others)	
	None		=
Lis	t any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
Lis	<u> </u>	cations and medical devices being used.	
	None		
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
	None		<u> </u>
S-6	ction F - About the Person Fil	ling Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		_
	Title		_
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
			_
	State/Province	UNITED STATES	
	ZIP or Postal code		_
	Telephone number	(b)(6)	
	Email address		

Generated by: SYSTEM Generated on: 08-Nov-2023 13:15:27 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-82545 | Department: CFSAN | RCT No.: RCT-1178394 | CTU Triage Date: 09-Nov-2023 | Total Pag

es: 7

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

Generated by: SYSTEM Generated on: 08-Nov-2023 13:15:27 Page 5 of 5

Ifactured by: AUSTROFOOO AV. Gral. Enriquez V Av. Gral. Enriquez V Av. Gral. Enriquez V Ichi (Esq.), Quito Ecuador. Ited in USA by: Wanabana (anabana USA, LLC 2113 W eet - Jacksonville FL 32209. eet - Jacksonville FL 32209.

ein cool dry place. Once med, refrigerate and sume within 5 days.

13 INEN 2337.

sm cap. This package has a sm cap. This product's cap shall opened under adult

- Hree Packaging

faily to eat

Wmore products visit:





Utrition Facts	4
Serving per package erving Size:	1 pouch (7)
mount per serving	6
Calories	50
	% Daily
Fotal Fat 0g	en l'ue
Saturated Fat 0g	%0
Trans Fat 0g	
Cholesterol Omg	%0
Sodium 0mg	%0
Total Carbohydrate 129	4%
Dietary Fiber 29	2%
Total Sugars 99	
Includes 0g Added Sugars	ars 0%
Protein 0g	
	%0
Vitamin D Umcg	/00
Calcium 4mg	60
Iron 0.2mg	00
Potassium 60mg	1
	an minent in a

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

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

NOT SUITABLE FOR MICROWAVE

Batch N° / Produced / Best by / see package



