CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

	Date the person stopped taking or using the product	20-Nov-2023			
	Date the person reduced dose of the product	20-Nov-2023			
	Give best estimate of duration				
	Is therapy still on-going?				
W	hy was the person using the pr	roduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Baby loves this babyfood eat ever	ry feeding after breast milk			<u> </u>
	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 expira	tion 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?				
Fc	or implanted medical devices O	NLY (such as pacemaker	rs, breast implants, etc.)		
=	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	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b)(6)			
	Weight	6.75 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati	ive		
		Native Hawaiian or Other Pacif			

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CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

		Asian	
		White	
		Black or African American	
Lis	st known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	NA		Т
Ple	ease list all allergies (such as	to drugs, foods, pollen or others)	
	peanut butter		T
Lis	t any other important informat	tion about the person (such as smoking, pregnancy, alcohol use, etc.)	
	NA		T
Lis	t all current prescription medi	cations and medical devices being used.	
	Amoxicillin 400mg Poly-vitamin/w	v iron solution	
Lis	t all over-the-counter medicat	tions and any vitamins, minerals, supplements, and herbal remedies being used.	
	NA		
Se	ction F - About the Person Fil	ling Out This Form 1 of 1	
	Primary?	Yes	Т
	Reporter is Patient?		\top
	Title		
	Last name	(b)(6)	
	Middle Name		T
П	First name	/I- \ / C \	
	Number/Street	(D)(D)	
П	City	(b)(6)	
	State/Province		
	Country	UNITED STATES	
П	ZIP or Postal code	(b)(c)	
	Telephone number	(b)(6)	
	Email address		\top

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CTU No.: FDA-CDER-CTU-2023-86494 | Department: CFSAN | RCT No.: RCT-1182393 | CTU Triage Date: 27-Nov-2023 | Total Pag

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

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CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag

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

ID : D / 1			
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	27-Nov-2023	CTU Received Date	27-Nov-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	·	
User/Group			
Forward to Department			
Case Priority	Direct		
	•		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b)(6)	(b)(6)	(b)(6)	(b)(6)	
Section A	- About the Problem				
	kind of problem was it? k all that apply)	1 1 I	effect (including new or worsening sympto	oms)	

1	ction A - About the Froblem	
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
	Date the problem occurred	13-Nov-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

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

My 20 month old son had a Wanabana cinnamon applesauce pouch on 11/13/2023. I didn't see the recall until the next day on the news. It was purchased back in September by my mother-in-law, possibly from Target. He may have had two since they typically come in packs of three and my sister-in-law said she may have been given one for her baby. My son had a lead blood test on 11/16/2023 and the results were 2.1 ug/dL. He had a lead blood test 5 months earlier on 06/01/2023 which was <1.0 ug/dL. We don't have the product. We have a picture of him eating the pouch but it's not clear enough to make out the lot number or exp date.

R	Relevant Test/Laboratory Data 1 of				
	Test Name	LEAD, WHOLE BLOOD	Test Date	01-Jun-2023	
	Test Result	<1.0	Test Unit	MICROGRAMS PER DEC	

CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag

	Low Test Range		High Test Range	
	More Information Available?			
Re	elevant Test/Laboratory Data			2 of 2
	Test Name	LEAD, WHOLE BLOOD	Test Date	16-Nov-2023
	Test Result	2.1	Test Unit	MICROGRAMS PER DEC
	Low Test Range		High Test Range	
	More Information Available?			
Ac	dditional 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)	Wananana Apple Cinnamo	on 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 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	rug Therapy			1 of 1
	Expiration date			

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CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pages: 5

	Lot number			
	Dosage Form			
	Quantity	If Other		
	Frequency	If Other		
	How was it taken or used	If Other		
	Date the person first started taking or using the product			
	Date the person stopped taking or using the product			
	Date the person reduced dose of the product			
	Give best estimate of duration			
	Is therapy still on-going?			
W	ny was the person using the pr	oduct? (such as what condition was it supposed to tre	eat) 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			
Ot	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the e	xpiration date, if you can	
IOC	eate them)			
	Model Number			
\vdash	Catalog Number Lot Number			
$\vdash \mid$	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem occurred?			
ΙFο	r implanted medical devices O	NLY (such as pacemakers, breast implants, etc.)		
Da	ate the implant was put in	Date the implant was taken out relevant)	(lf	
22	ction F - About the Person Wh	no Had the Problem		
Se	ction E - About the Person Wh	no Had the Problem		
Se	ction E - About the Person Wh Person's Initials Sex			

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CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pag

Please Specify Other Gender		
Age (specify unit of time for age)	20 Month(s)	
Date of Birth		
Weight		
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
List known medical conditions (S	uch as diabetes, high blood pressure, cancer, heart disease, or others)	
Please list all allergies (such as t		
	arage, recae, penerrer enterey	
List any other important informati	on about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription medic	ations and medical devices being used.	
List all over-the-counter medication	ons and any vitamins, minerals, supplements, and herbal remedies being used.	
Section F - About the Person Filli	ing Out This Form 1 of 1	
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
I Middle Name		

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CTU No.: FDA-CDER-CTU-2023-86810 | Department: CFSAN | RCT No.: RCT-1182791 | CTU Triage Date: 28-Nov-2023 | Total Pages: 5

Number/Street	
City	(h)(6)
State/Province	(b)(6)
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(h)(6)
Email address	(b)(6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	27-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):	Yes

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CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-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	<u>'</u>	
Override Auto Calculation Rule	No		
FDA Received Date	28-Nov-2023	CTU Received Date	28-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-C	DSE-RSS-CTU@fda.hhs.gov) (E2B)	
Case Priority	Direct		

Co	ontact						
-	ase eporter	First Name		Last Name	Email Address	Phone	
<u> </u>		(b)(6)		(b)(6)	(b)(6)	(b)(6)	
Se	ection A	- About the F	Problem				
		nd of problem vall that apply)	was it?	Used a product incorrectly Noticed a problem with the	e effect (including new or worsening which could have or led to a problem quality of the product	n	
	Date the	problem occu	ırred	28-Nov-2023			
	Serious			Yes			
		of the following	g happen?	Hospitalization - admitted of Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important me	ermanent harm	w)	
		erious/importar (Please Descri	I				
4. ar	Fig. 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's	s lead level is e	elevated afte	er he consumed the cinna	mon applesauce pouches fro	om WanaBana.	

ĮRε	elevant Test/Laboratory Data	1 of 1			
	Test Name	LEAD TEST	Test Date	28-Nov-2023	
	Test Result	8.0	Test Unit	MICROGRAMS PER DEC	

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CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pag

	Low Test Range	0	High Test Range	3.5	
	More Information Available?				
Ad	ditional Comments				
0.0	ation D. Duodunt Ameilahilitu				
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)	WanaBana cinnamon apple	sauce 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?				
	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	01-Jan-2023			

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CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

	Date the person stopped taking or using the product	01-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	roduct? (such as what condition was it supposed to 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		
	her identifying information (The	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?		
ΙFο	r implanted medical devices O	NLY (such as pacemakers, 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	(p)(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)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

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CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

		Asian White Black or African American	
Lis	t known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
ĮΡΙ	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	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	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)	
_	51.19		_
_	State/Province Country	UNITED STATES	_
_	-		_
_	Telephone number	(b)(6)	
_	Email address		

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CTU No.: FDA-CDER-CTU-2023-87189 | Department: CFSAN | RCT No.: RCT-1183168 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	28-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	

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CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pag

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

More Information Available?

Basic Deta	ils						
Company U	nit	CDER-CTU	Originating Account	FAERS			
Source Med	lium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority		Routine	•				
Override Au	to Calculation Rule	No					
FDA Receiv	ed Date	29-Nov-2023	CTU Received Date	29-Nov-2023			
CTU Triage	Date		CTU Data Entry Date				
Report Type)	Spontaneous	Report Classification	Drug			
Assign To		User		·			
User/Group							
Forward to I	Department	CDER (CDER-OSE-R	SS-CTU@fda.hhs.gov) (E2	2B)			
Case Priorit	у	Direct	<u> </u>	,			
Contact							
Case Reporter	First Name	Last Name	Email Address	Phone			
	(b)(6)	(b)(6)	(b)(6)	(b)(6)			
Section A -	About the Problem						
	id of problem was it?	[Z]					
	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	01-Nov-2023					
Serious	<u> </u>	No					
Did any	of the following happen?	Hospitalization - admitted or stayed longer					
(Check a	all that apply)	Required help to prevent permanent harm					
		Disability or health problem					
		Birth defect					
		Life-threatening					
		Death					
		Other serious/important medic	cal incident(Please Describe Below	v)			
4.Tell us w	hat happened and ho	w it happened (Include a	s many details as possi	ble FDA may reach out to you for			
	nal documents if nece	-	har blood Javal 7				
Daugnte	r consumed a recalled pr	oduct and lead was found in	ner blood - level 7.				
Relevant T	est/Laboratory Data			1 of 1			
Test Nar	·	PEDIATRIC LEAD SCREE	Test Date	01-Nov-2023			
Test Res	sult	7	Test Unit	GRAMS PER DECILITER			
Low Tes	t Range	0	High Test Range	3.4			

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CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pag

ΙAc	Iditional Comments				
7 10	antional 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)	Apple Cinnamon 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 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	Daily	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				

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CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

	Give best estimate of duration	2 Month	
	Is therapy still on-going?		
WI	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Transition to solid foods		
	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	
100	cate them)		
	Model Number		_
	Catalog Number		_
	Lot Number		_
\vdash	Serial Number		_
	UDDI Number		_
	Expiration date		_
	Was someone operating the		
	medical device when the problem occurred?		
L E		NLY (such as pacemakers, breast implants, etc.)	
_	ate the implant was put in	Date the implant was taken out (If	
	ate the implant was put in	relevant)	
Se	ection 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	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		Plack or African American	

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CTU No.: FDA-CDER-CTU-2023-87260 | Department: CFSAN | RCT No.: RCT-1183250 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

lı :	*	\\\\dish-4\dish-bld\dish	
LIS	<u> </u>	Such as diabetes, high blood pressure, cancer, heart disease, or others)	<u> </u>
	Sickle cell trait		
DI	saas list all alleraise (auch as	to drugs, foods, pollen or others)	
PIE		to drugs, loods, pollen or others)	
	Dairy		
ll is	t any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
		ion about the person (such as smoking, pregnancy, accordingse, etc.)	_
	Baby		
Lis	t all current prescription medi	cations and medical devices being used.	
	N/a		$\overline{}$
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
	N/a		T
٥٩	ction F - About the Person Fil	ling Out This Form 1 of 1	
	Primary?	Yes	
		1 es	+
\square	Reporter is Patient?		_
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(b)(C)	
	Number/Street	(b)(6)	
	City		
	State/Province		+
\vdash	Country	UNITED STATES	+
	ZIP or Postal code		+
		(b)(6)	1
	Telephone number		_
	Email address		
	Fax		
	Reporter Organization		

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es: 5

Department		
Reporter Speciality		
Today's date	29-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	

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CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-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		<u>'</u>			
Override Auto Calculation Rule	No					
FDA Received Date	29-Nov-2023	CTU Received Date	29-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-O	SE-RSS-CTU@fda.hhs.gov) (E2B)				
Case Priority	Direct	<u> </u>				
Contact						
Case First Name	Last Name	Email Address	Phone			
Reporter (b)(6)	/b\/C\	(1-)(0)	(1-)(0)			
(b)(6)	(b)(6)	(b)(6)	(b)(6)			
Section A - About the Problem						
What kind of problem was it?	[7					
(Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)					
		Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product				
	Had problems after switching from one product maker to another maker					
Date the problem occurred	06-Nov-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 how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)						
My son consumed WanaBana Cinnamon Applesauce pouches prior to the recall. After recall notice was released, lead blood						
	test was performed and result was elevated. Only known exposure was the recalled pouches. Plan to retest (via venipuncture, not capillary) at beginning of January 2024 to evaluate if level is still elevated.					

ΙR	Relevant Test/Laboratory Data 1 of 1					
	Test Name	LEAD, CAPILLARY	Test Date	06-Nov-2023		
	Test Result	11	Test Unit	MICROGRAMS PER DEC		
	Low Test Range	0	High Test Range	3		

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CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pag

es: 5

	More Information Available?				
Ac	lditional 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)	WanaBana Apple Cinnamor	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				
	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	01-Aug-2023			
	Date the person stopped taking	29-Oct-2023			

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CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

	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 Snack	oduct? (such as what con	dition was it supposed to 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	her identifying information (The cate them)	e model, catalog, lot, seria	l, or UDI number, and the expirat	tion 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	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	10.35 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific			

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CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pag

	White Black or African American	
List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
None		
Please list all allergies (such as	to drugs, foods, pollen or others)	
None		
List any other important informa	ation about the person (such as smoking, pregnancy, alcohol use, etc.)	
List all current prescription med	ications and medical devices being used.	
List all over-the-counter medica	tions and any vitamins, minerals, supplements, and herbal remedies being used.	
	11. O (T): F	
Section F - About the Person F Primary?	Illing Out This Form 1 of 1 Yes	
Reporter is Patient?		+
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	(h)(6)	
Telephone number	(b)(6)	_
Email address		

CTU No.: FDA-CDER-CTU-2023-87356 | Department: CFSAN | RCT No.: RCT-1183358 | CTU Triage Date: 29-Nov-2023 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	29-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	

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CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pag

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

Other serious/important medical incident(Please Describe Below)

	rt 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	on Rule No				
FDA Received Date	29-Nov-2023	CTU Received Date	29-Nov-2023		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User		'		
User/Group					
Forward to Department	☑ cder (cde	:R-OSE-RSS-CTU@fda.hhs.gov) (E2B)			
Case Priority	Direct	3 , (,			
Reporter (b)(6)	(b)(6)	(b)(6)	(b)(6)		
		(5)(6)	(-)(-)		
Section A - About the					
What kind of problen (Check all that apply		Were hurt or had a bad side effect (including new or worsening symptoms)			
(Check all that apply	Used a product in	ncorrectly which could have or led to a problem			
	Noticed a problem	Noticed a problem with the quality of the product			
	Had problems after	Had problems after switching from one product maker to another maker			
Date the problem oc	curred 04-Nov-2023				
Serious	Yes				
Did any of the follow		admitted or stayed longer			
(Check all that apply)	Required help to prevent permanent harm			
	Disability or health				
	Birth defect				
	Life-threatening				
	Death				

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)

Other serious/important medical incident(Please Describe Below)

My 2 year old ate the Wana Bana applesauce pouches purchased from Dollar Tree in (b)(6) and had an elevated blood lead level of 6.7 on November 7. At his 2 year old screening in March his level was <1. The pouches were purchased and consumed in July, August and September. He did not have any of that brand of pouch in October.

F	Relevant Test/Laboratory Data			1 of 1	
	Test Name	BLOOD LEAD LEVEL	Test Date	04-Nov-2023	
	Test Result	6.7	Test Unit	GRAMS PER DECILITER	

CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pag

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C	5		U

	Low Test Range		High Test Range		
	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	No No			
	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)	Cinnamon applesauce			
	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?				
Dru	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	11-Jul-2023			

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CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pag

	Date the person stopped taking or using the product	28-Sep-2023			
	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 cor	ndition was it supposed to 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				
	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expira	tion 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?				
Fc	or implanted medical devices C	NLY (such as pacemaker	rs, breast implants, etc.)		
=	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	13.5 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			_
	Race (Check all that apply)	American Indian or Alaska Nati	ive		
		Native Hawaiian or Other Pacif			

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CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pages: 5

		Asian White Black or African American	
Lis	t known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Pl€	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	cations and medical devices being used.	
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being use	d.
Se	ction F - About the Person Fil	ling Out This Form 1 of 1	1
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b)(6)	
	Middle Name		
	First name	(h)(6)	
	Number/Street	(b)(6)	
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(h)(6)	
	Telephone number	(b)(6)	
	Email address		

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CTU No.: FDA-CDER-CTU-2023-87451 | Department: CFSAN | RCT No.: RCT-1183426 | CTU Triage Date: 30-Nov-2023 | Total Pag

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	29-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	

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CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pag

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

Basic Deta	ils						
Company U	nit	CDER-CTU		nating Account	FAERS		
Source Med	lium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500B		
Priority		Routine					
Override Auto Calculation Rule		No					
FDA Received Date		29-Nov-2023	CTU	Received Date	29-Nov-2023	29-Nov-2023	
CTU Triage	Date		CTU	Data Entry Date			
Report Type	9	Spontaneous	Repo	ort Classification	Drug		
Assign To		User	'				
User/Group							
Forward to	Department	CDER (CDER	-OSE-RSS-CT	U@fda.hhs.gov) (E2B)			
Case Priorit	у	Direct		5 / (
Contact							
Case	First Name	Last Name		Email Address	Phone		
Reporter	(b)(6)	(b)(6)		(b)(6)	(b)(6)	_	
	(6)(6)			(6)(0)	(6)(0)	_	
Section A -	About the Problem						
	nd of problem was it? all that apply)	Used a product inco	rrectly which could				
Date the	problem occurred	Had problems after switching from one product maker to another maker 24-Oct-2023					
Serious		Yes					
	of the following happen? all that apply)	Hospitalization - adr	event permanent ha				
incident(rious/important medical Please Describe Below)						
4.Tell us w any additio	hat happened and how nal documents if nece	w it happened (Inc essary)	lude as man	y details as possible F	DA may reach out to you for		
Consum	ed 4 Wanabana cinnamo	n pouches. Confirme	ed elevated bloo	od lead level.			

F	lelevant Test/Laboratory Data 1 of 1				
	Test Name	VENOUS BLOOD LEAD T EST	Test Date	08-Nov-2023	
	Test Result	13.6	Test Unit	MILLIGRAMS PER DECIL ITRE	

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CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pag

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	Low Test Range		High Test Range		
	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	No No			
	product? (check yes if you are 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)	WanaBana apple cinnamor	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				
	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?				
Dru	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form		1		
	Quantity	Other		4 pouches	
	Frequency	4 times a day	If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product	24-Oct-2023			

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CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pages: 5

	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?		
W	ny was the person using the pr	roduct? (such as what condition was it supposed to 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		
Ot		e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	eate 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 C	NLY (such as pacemakers, 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	(6)(8)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	5 Year(s)	
	Date of Birth		
	Weight	18.9 kg	
	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

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CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pag

	Asian White	
	Black or African American	
List known medical condition	ons (Such as diabetes, high blood pressure, cancer, heart disease, or others)	
	<u> </u>	
Please list all allergies (suc	ch as to drugs, foods, pollen or others)	
dairy		
List any other important info	ormation about the person (such as smoking, pregnancy, alcohol use, etc.)	
anemia was diagnosed	5/1 5 3/	
List all current prescription	medications and medical devices being used.	
l ist all over-the-counter me	edications and any vitamins, minerals, supplements, and herbal remedies being u	used
flintstones multi-vitamins	у в том в то	
Section F - About the Perso		of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b)(6)	
Middle Name		
First name	(b)(6)	
Number/Street		
City		
State/Province	(b)(6)	
Country	UNITED STATES	
ZIP or Postal code	(b)(c)	
Telephone number	(b)(6)	
Email address	()	

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CTU No.: FDA-CDER-CTU-2023-87460 | Department: CFSAN | RCT No.: RCT-1183446 | CTU Triage Date: 30-Nov-2023 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	29-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	

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CTU No.: FDA-CDER-CTU-2023-87513 | Department: CFSAN | RCT No.: RCT-1183492 | CTU Triage Date: 30-Nov-2023 | Total Pag

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

Company Unit CDER-CTU Originating Account FAERS Source Medium MWO (Drug) Source Form Type E2B XML 35008 Priority Routine Override Auto Calculation Rule No FDA Received Date 30-Nov-2023 CTU Received Date 30-Nov-2023 CTU Data Entry Date FOUND FOR THE PRIOR FOR THE PRI	Dac	sic Detai							
Priority	Со	mpany U	nit	CDE	ER-CTU	Origi	nating Account	FAERS	
Override Auto Calculation Rule FDA Received Date So-Nov-2023 CTU Triage Date Spontaneous Report Type Spontaneous Assign To User User User/Group Forward to Department Case Priority Direct Case Priority Direct Contact Case Priority Contact Case First Name Last Name Email Address Phone Phone What kind of problem was it? (Check all that apply) Used a product incorrectly which could have or led to a problem What kind of problem was it? (Check all that apply) Date the problem occurred Serious No Did any of the following happen? (Check all that apply) Required help to prevent permanent harm Disability or health problem Bith defect Used a product incorrectly which could have or led to a problem waker Required help to prevent permanent harm Disability or health problem Death Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Death Other serious/important medical inddent/Please Describe Below) 4-Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Pure Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Range High Test Range	Soi	urce Med	ium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B	
FDA Received Date 30-Nov-2023 CTU Triage Date Report Type Spontaneous Report Classification Drug Assign To User User/Group Forward to Department Case Priority Direct Contact Case Priority C	Pri	ority		Rou	tine				
CTU Triage Date Report Type Spontaneous Report Classification Drug Assign To User User User(Group Forward to Department Case Priority Direct Case Pr	Ov	erride Au	to Calculation Rule	No					
Report Type	FD	A Receiv	ed Date	30-Nov-2023		CTU	Received Date	30-Nov-2023	
Assign To User User/Group Forward to Department Coper (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)	CTU Triage Date				CTU	Data Entry Date			
User/Group Fonward to Department Case Priority Direct Contact	Re	port Type)	Spo	ntaneous	Repo	ort Classification	Drug	
Contact	Ass	sign To		Use	r				
Case Priority Direct	Use	er/Group							
Contact Case First Name Last Name Email Address Phone	For	rward to [Department	\overline{Z}	CDER (CDER-OSE-RS	SS-CT	U@fda.hhs.gov) (E2B)		
Case Reporter Case First Name Last Name Email Address Phone	Ca	se Priorit	у						
Case Reporter Case First Name Last Name Email Address Phone									
Reporter (b)(6) Section A - About the Problem What kind of problem was it? (Check 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 Serious No Did any of the following happen? (Check all that apply) 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 how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result High Test Range	Cor	ntact							
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			First Name		Last Name		Email Address	Phone	
Section A - About the Problem What kind of problem was it? 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			(b)(6)		(b)(6)				
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 Serious No Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Name High Test Range High Test Range	Δ		(b)(b)		(p)(o)				
Check all that apply Sued 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	Sec	ction A -	About the Problem						
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					Were hurt or had a bad side ef	fect (incl	uding new or worsening symptoms)		
Date the problem occurred Serious No Did any of the following happen? (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 how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Low Test Range High Test Range		(Check a	ill that apply)						
Date the problem occurred Serious No Did any of the following happen? (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 how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Low Test Range High Test Range									
Serious Did any of the following happen? Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data					Had problems after switching from one product maker to another maker				
Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Date Test Name Test Date Test Result Test Unit Low Test Range High Test Range		Date the	problem occurred						
(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 how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data		Serious		No					
Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data 1 of 1 Test Name Test Date Test Result High Test Range High Test Range				Hospitalization - admitted or stayed longer					
Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data 1 of 1 Test Name Test Date Test Result Low Test Range High Test Range		(Cneck a	ili that apply)						
Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data									
Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Low Test Range High Test Range					Birth defect				
A.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Test Unit Low Test Range High Test Range				Щ	_ife-threatening				
4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you fany additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Test Unit Low Test Range High Test Range					Death				
Any additional documents if necessary) My daughter has had several of the WanaBana Apple Cinnamon Fruit Puree Pouches. Her last 2 pouches were on 11/10/23. Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data Test Name Test Date Test Result Low Test Range High Test Range					· · · · · · · · · · · · · · · · · · ·				
Then found out on the 11/15/23 they were recalled. Got her tested on 11/17/23 for lead testing and has elevated lead level. Relevant Test/Laboratory Data	4.Te	ell us wl ⁄ additio	nat happened and how nal documents if nece	wit h ssar	appened (Include as y)	man	/ details as possible FDA r	nay reach out to you fo	or
Relevant Test/Laboratory Data Test Name Test Date Test Result Low Test Range High Test Range									
Test Name Test Date Test Result Test Unit Low Test Range High Test Range		Then fou	ind out on the 11/15/23 th	ney w	ere recalled. Got her tes	ited on	11/17/23 for lead testing and h	nas elevated lead level.	
Test Name Test Date Test Result Test Unit Low Test Range High Test Range									
Test Name Test Date Test Result Test Unit Low Test Range High Test Range									
Test Name Test Date Test Result Test Unit Low Test Range High Test Range									
Test Result Low Test Range High Test Range	Rel	evant T	est/Laboratory Data			T		1 of 1	
Low Test Range High Test Range		Test Nar	ne			Test	Date		
		Test Res	sult			Test	Unit		
More Information Available?		Low Tes	t Range			High	Test Range		
		More Info	ormation Available?						

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ΙΛο	ditional Comments				
AC	utional 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)	WanaBana Apple Cinnamo	n Fruit Puree 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?				
	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		ı		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started taking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of				

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the product

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	Give best estimate of duration		
	Is therapy still on-going?		
WI	ny was the person using the pr	roduct? (such as what condition was it supposed to 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		
Ot	her identifying information (The ate 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 C	DNLY (such as pacemakers, breast implants, etc.)	
_	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)(8)	
	Sex	Female	
	Gender	Not selected	
	Please Specify Other Gender		
	Age (specify unit of time for age)	3 Year(s)	
	Date of Birth		
	Weight		
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	

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CTU No.: FDA-CDER-CTU-2023-87513 | Department: CFSAN | RCT No.: RCT-1183492 | CTU Triage Date: 30-Nov-2023 | Total Pages: 5

Lis	st known medical conditions (S	Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	to drugs, foods, pollen or others)	
			$\overline{\top}$
ll ic	at any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	
LIS	st any other important informat	ion about the person (such as smoking, pregnancy, alcohol use, etc.)	T
Lis	st all current prescription medic	cations and medical devices being used.	
Lis	st all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Lis	st all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Lis	st all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
Lis	t all over-the-counter medicat	ions and any vitamins, minerals, supplements, and herbal remedies being used.	
	et all over-the-counter medicat		
	ection F - About the Person Fill	ing Out This Form 1 of 1	
	ection F - About the Person Fill Primary?	ing Out This Form 1 of 1	
	ection F - About the Person Fill Primary? Reporter is Patient?	ing Out This Form 1 of 1	
	ection F - About the Person Fill Primary? Reporter is Patient? Title	ing Out This Form 1 of 1 Yes	
	ection F - About the Person Fill Primary? Reporter is Patient? Title Last name	ing Out This Form 1 of 1 Yes	
	ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name	ing Out This Form 1 of 1 Yes (b)(6)	
	ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	ing Out This Form 1 of 1 Yes (b)(6)	
	Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	ing Out This Form 1 of 1 Yes (b)(6)	

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es: 5

Department		
Reporter Speciality		
Today's date	30-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	

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CTU No.: FDA-CDER-CTU-2023-88329 | Department: CFSAN | RCT No.: RCT-1184253 | CTU Triage Date: 04-Dec-2023 | Total Pag

incident(Please Describe Below)

All dates displa	yed in the report are in EST(G	MT-05	:00) time zone						
Basic Deta	ils								
Company U	Init	CDE	ER-CTU	Originating Account			FAERS		
Source Medium		MWO (Drug) Source Form Type			E2B XML 3500B				
Priority		Rou	Routine						
Override Au	uto Calculation Rule	No	No						
FDA Receiv	/ed Date	01-0	-Dec-2023 CTU Received Date		01-Dec-2023				
CTU Triage	Date			CTU	Data Entry Date				
Report Typ	е	Spo	ntaneous	Repo	ort Classification	Drug			
Assign To		Use	r						
User/Group	1								
Forward to	Department	\square							
Case Priori	ty	Dire	ct						
Contact									
Case First Name Reporter		Last Name Er		Email Address		Phone			
(b)(6)		(b)(6)			(b)(6)				
Section A	- About the Problem								
What kind of problem was it? (Check all that apply)		Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker							
Date the problem occurred		27-Nov-2023							
Serious		Yes					_		
Did any of the following happen? (Check all that apply)			Hospitalization - admitted or sta Required help to prevent perm. Disability or health problem Birth defect Life-threatening Death Other serious/important medica	anent ha	arm				
Other serious/important medical					•				

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 had fed our two children WanaBana cinnamon applesauce from the Dollar Store for about the last 12 months. The children are ages 5 and 6. They have routine blood work ups and have never had detectable lead levels. Given the newly reported lead reports in this product which I learned about on 11/26, I took both in on Monday the 27th to be tested. Both tested with elevated lead levels. The 5 year old was 6.1 and the 6 year old was 2.6. Reports are available.

ĮR€	Relevant Test/Laboratory Data				
	Test Name	LEAD	Test Date	17-Jan-2019	
	Test Result	None detected	Test Unit		
	Low Test Range		High Test Range		

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

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	Date the person reduced dose of the product				
	Give best estimate of duration				
	Is therapy still on-going?	_			
W	ny was the person using the pr	roduct? (such as what con	dition was it supposed to tr	reat) 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	e model, catalog, lot, seria	ıl, or UDI number, and the e	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 pacemaker	s, breast implants, etc.)		
Da	ate the implant was put in		Date the implant was taken ou relevant)	it (If	
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	Unspecified			
	Sex	Male			
	Gender	Cisgender man/boy			
	Please Specify Other Gender				
	Age (specify unit of time for age)	6 Year(s)			
	Date of Birth				
	Weight				
	Ethnicity (Choose only one)				
	Race (Check all that apply)	American Indian or Alaska Natir			

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1 1		
	White	
	Black or African American	
	(C	
List known medical conditions	(Such as diabetes, high blood pressure, cancer, heart disease, or others)	
Disease list all allergies (auch s	e te dui un feede vellev ev ethevel	
Please list all allergies (such as	s to drugs, foods, pollen or others)	
List any other important inform	nation about the person (such as smoking, pregnancy, alcohol use, etc.)	
List any other important inform	ation about the person (such as smoking, pregnancy, accordings, etc.)	
List all current prescription med	dications and medical devices being used.	
List all current prescription med	dications and medical devices being used.	
I jet all ever the counter modic	ations and any vitamins, minerals, supplements, and herbal remedies being u	aad
List all over-the-counter medica	ations and any vitamins, minerals, supplements, and herbarremedies being d	seu.
Section F - About the Person F	Filling Out This Form 1 c	of 1
Section F - About the Person F	Filling Out This Form 1 c	of 1
<u></u>		of 1
Primary?		of 1
Primary? Reporter is Patient?		of 1
Primary? Reporter is Patient? Title	Yes	of 1
Primary? Reporter is Patient? Title Last name	Yes (b)(6)	of 1
Primary? Reporter is Patient? Title Last name Middle Name	Yes (b)(6)	of 1
Primary? Reporter is Patient? Title Last name Middle Name First name	Yes	of 1
Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	Yes (b)(6)	of 1
Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	Yes (b)(6)	of 1
Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	(b)(6) (b)(6) UNITED STATES	of 1
Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	(b)(6) (b)(6)	of 1

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Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	01-Dec-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	

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