

CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag

| Il dates displayed in the report are in EST(G | MT-05:00) time zone | | | | | | | |
|--|--|--------------------------------------|-------------|--|--|--|--|--|
| Basic Details | | | | | | | | |
| Company Unit | CDER-CTU | Originating Account Source Form Type | FAERS | | | | | |
| Source Medium | MWO (Drug) | E2B XML 3500 | | | | | | |
| Priority | Routine | | | | | | | |
| Override Auto Calculation Rule | No | | | | | | | |
| FDA Received Date | 17-Nov-2023 | CTU Received Date | 17-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 First Name | Last Name | Email Address | Phone | | | | | |
| Reporter (b)(6) | (b)(6) | (b)(6) | (b)(6) | | | | | |
| <u>(ρ)(ρ)</u> | (6)(6) | (6)(6) | (8)(8) | | | | | |
| A. PATIENT INFORMATION | | | | | | | | |
| Patient Identifier (In Confidence) | (b)(6) | | | | | | | |
| Age | 21 Month(s) | | | | | | | |
| Date of Birth | | | | | | | | |
| Sex | Female | | | | | | | |
| Gender | Cisgender woman/girl | | | | | | | |
| Please Specify Other Gender | | | | | | | | |
| Weight | | | | | | | | |
| Ethnicity (Check single best answer) | Not Hispanic/Latino | | | | | | | |
| Race (Check all that apply) | Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander | | | | | | | |
| 3. ADVERSE EVENT, PRODUC | T PROBLEM | | | | | | | |
| Type of Report (check all that apply) | Adverse Event Product Use/Medication Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine | | | | | | | |
| Serious | Yes | | | | | | | |
| Outcome Attributed to Adverse Event (Check all that apply) Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage | | | | | | | | |

Generated by: SYSTEM Generated on: 17-Nov-2023 15:15:33 Page 1 of 4

CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag

| | | Congenital Anomaly/Birth Defects | | | | | | |
|-----|--|---|---|--|--|--|--|--|
| | | Required Intervention to Prevent Permanent Impairment/Damage | | | | | | |
| | Date of Death | | | | | | | |
| | Date of Event | 25-Oct-2023 | 25-Oct-2023 | | | | | |
| | Date of this Report | 17-Nov-2023 | | | | | | |
| De | scribe Event, Problem or Prod | luct Use Error | | | | | | |
| | Cinnamon Fruit Puree from Dollar from the Dollar Tree located at eit she shops at both locations but ca dates her child consumed the three her child's pediatrician to arrange | Tree around 10/23/23. Mother (b)(6) an't remember which location be pouches of puree but upon for a blood test. The pediatric | reports that she purchased the War er reports that she purchased a thre she purchased this product from. M hearing the recall information on the cian's office contacted the health dep hat the child was tested because the | e pouch pack of the product . Mother states other can't remember exact e news mother contacted partment via phone on | | | | |
| Re | elevant Test/Laboratory Data | | | 1 of 1 | | | | |
| | Test Name | VENOUS BLOOD LEAD T EST | Test Date | 08-Nov-2023 | | | | |
| | Test Result | 7.9 | Test Unit | MICROGRAMS PER DEC | | | | |
| | Low Test Range | | High Test Range | > 3.5 mcg/dL | | | | |
| | More Information Available? | | | | | | | |
| Ac | lditional Comments | | | | | | | |
| | Child had previously been tested | for lead in March 2023 and di | d not have an elevated blood lead le | evel. | | | | |
| lOt | her Relevant History, Including | Preexisting Medical Con | nditions | | | | | |
| | No pre-existing health conditions | | Millons | | | | | |
| C. | PRODUCT AVAILABILITY | | | | | | | |
| | Product Available for Evaluation? (Do not send product to FDA) | No | | | | | | |
| | Returned to Manufacturer on | | | | | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | No | | | | | | |
| D. | PRODUCT(S) | | | 1 of 1 | | | | |
| | Suspect | Yes | | | | | | |
| | Primary? | Yes | | | | | | |
| | Туре | Drug/Biologic | | | | | | |
| | This report involves: | Food/Medical food | | | | | | |
| Na | me,Strength,Manufacturer/Co | mpounder (from product l | label) | | | | | |
| | Product Name | Wana Bana Apple Cinnamo | on Fruit Puree | | | | | |

Generated by: SYSTEM Generated on: 17-Nov-2023 15:15:33 Page 2 of 4

CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag

233 G gram(s) If Other Strength Manufacturer/Compounder Wana Bana NDC# or Unique ID Product Type(check all that Отс apply) Compounded Generic Biosimilar Event Abated After Use Stopped Doesn't Apply or Dose Reduced? Event Reappeared after Doesn't Apply Reintroduction? Drug Therapy Dose or Amount If Other If Other Frequency Oral If Other Route Dosage Form Start Stop Dose Reduced Therapy Duration If Other Is therapy still on-going? Lot Number **Expiration Date** Diagnosis for Use (indication) 1 of 1 E. SUSPECT MEDICAL DEVICE **Brand Name** Common Device Name Procode Manufacturer Name City State Model# Lot# Catalog # **Expiration Date** Serial # Unique Identifier (UDI)# Operator of Device Health Professional Patient/Consumer

Generated by: SYSTEM Generated on: 17-Nov-2023 15:15:33 Page 3 of 4

Other

CTU No.: FDA-CDER-CTU-2023-84966 | Department: CFSAN | RCT No.: RCT-1180909 | CTU Triage Date: 17-Nov-2023 | Total Pag

| | Other | | | | | | |
|----|---|---|-----|----------|---|--------|--|
| | If Implanted, Give Date | | | | | | |
| | If Explanted, Give Date | | | | | | |
| | Is this a single-use device that was reprocessed and reused on a patient? | | | | | | |
| | If Yes for the above field, Enter Name and Address of Reprocessor | | | | | | |
| | Was this device serviced by a third party? | | | | | | |
| F. | OTHER (CONCOMITANT) ME | EDICAL PRODUC | TS | | | | |
| | 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 | (D)(D) | | | | | |
| | City | | | | | | |
| | State/Province/Region | | | | | | |
| | Country | UNITED STATES | | If Other | | | |
| | ZIP/Postal Code | 11-110 | 11 | | | | |
| | Phone | (b)(6 |)] | | | | |
| | Email | | - / | | | | |
| | Fax | | | | | | |
| | Reporter Organization | | | | | | |
| | Department | | | | | | |
| | Reporter Speciality | | | | | | |
| | Health Professional? | Yes | | | | | |
| | Occupation | Nurse | | If Other | | | |
| | Also Reported to | Manufacturer/C User Facility Distributor/Impo | | nder | , | | |
| | If you do NOT want your identity disclosed to the manufacturer | No | | | | | |

Generated by: SYSTEM Generated on: 17-Nov-2023 15:15:33 Page 4 of 4

Last Name

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pag

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

Contact

Case

First Name

any additional documents if necessary)

| 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 | 19-Nov-2023 | CTU Received Date | 19-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 | | | | | | | |
| | | | | | | | | |

Email Address

Phone

| ₽ ₽ | (b)(6) | (b)(6) | (b)(6) | (b)(6) | _ |
|--------|---|---|--|-----------------------------|---|
| Se | ection A - About the Problem | | | | |
| | What kind of problem was it? (Check all that apply) | Used a product incorred Noticed a problem with | side effect (including new or worsening sympt ctly which could have or led to a problem the quality of the product tching from one product maker to another mak | | |
| | Date the problem occurred | 20-Sep-2023 | | | |
| | Serious | No | | | |
| | Did any of the following happen? (Check all that apply) | Required help to prever Disability or health prob Birth defect Life-threatening Death | nt permanent harm | | |
| 4. | Fell us what happened and ho | w it happened (Includ | de as many details as possible f | DA may reach out to you for | |

WanaBana apple cinnamon fruit pouches: On September 20th at her 2yr old appointment my daughter tested positive for high levels of lead by capillary finger prick with level 21.5. She was retested by venous blood draw on September 28th and still tested positive for high levels of lead with level of 21.0. An abdomen X-ray was done on October 2nd for foreign object containing lead and large amount of stool throughout the colon was found so she was treated for constipation- no foreign object was found. On October 25th she was tested yet again and was positive for high levels of lead; this time her level was 25.4. After hearing that WanaBana fruit pouches was the cause of several other children testing for high levels of lead we concluded this was the reason for the spike in her lead levels. The last time she ate the tainted product was October 19th and she ate 3 of them that day as well as multiple previous days. This was approximately a week before she was tested on October 25th. My husband and I were also tested and our tests came back as normal- we never ate any of the apple pouches. Upon research high levels can cause cognitive impairment, irritability, constipation among other issues including death. This is a serious matter of my young child's health! I can't believe something so toxic that's geared towards babies, toddlers and young children fell through the cracks and now has affected my child and others. My daughter still will have to undergo many tests to check her lead levels because of the tainted product as well as who knows what else she will have to go through because lead effects so many different parts of the body. So sad to lose complete faith in a company that was once my child's favorite snack.

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pag

es: 7

| elevant Test/Laboratory Data | | | 1 of 4 |
|--|--|-----------------|--------------------|
| Test Name | LEAD CAPILLARY | Test Date | 20-Sep-2023 |
| Test Result | 21.5 | Test Unit | MICROGRAMS PER DEC |
| Low Test Range | | High Test Range | |
| More Information Available? | | | , |
| elevant Test/Laboratory Data | | | 2 of 4 |
| Test Name | LEAD BLOOD VENOUS | Test Date | 28-Sep-2023 |
| Test Result | 21.0 | Test Unit | MICROGRAMS PER DEC |
| Low Test Range | | High Test Range | |
| More Information Available? | | | J |
| elevant Test/Laboratory Data | | | 3 of 4 |
| Test Name | XR ABDOMEN | Test Date | 02-Oct-2023 |
| Test Result | Large amount of stool thro ughout the colon. | Test Unit | |
| Low Test Range | | High Test Range | |
| More Information Available? | | | J |
| elevant Test/Laboratory Data | | | 4 of 4 |
| Test Name | LEAD BLOOD VENOUS | Test Date | 25-Oct-2023 |
| Test Result | 25.4 | Test Unit | MICROGRAMS PER DEC |
| Low Test Range | | High Test Range | |
| More Information Available? | | | 1 |
| dditional Comments | | | |
| | | | |
| | | | |
| | | | |
| ection B - Product Availability | | | |
| Do you still have the product in case we need to evaluate it? | Yes | | |
| Do you have a picture of the product? (check yes if you are including a picture) | Yes | | |
| ection C - About the Products | | | 1 of 1 |
| Suspect | Yes | | |
| Suspeci | | | |
| Primary? | Yes | | |
| | Yes Drug/Biologic | | |
| Primary? | | | |

Generated by: SYSTEM Generated on: 19-Nov-2023 22:15:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pages: 7

| | 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 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? | Yes | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | 30-Mar-2024 | | | |
| | Lot number | 01023:30 | | | |
| | Dosage Form | | | | |
| | Quantity | Other | If Other | 1 7.50oz | |
| | Frequency | Other | If Other | Every day | |
| | How was it taken or used | Oral | If Other | | |
| | Date the person first started taking or using the product | 10-Oct-2022 | | | |
| | Date the person stopped taking or using the product | 19-Oct-2023 | | | |
| | Date the person reduced dose of the product | | | | |
| | Give best estimate of duration | | | | |
| | Is therapy still on-going? | Yes | | | |
| WI | ny was the person using the pr | oduct? (such as what co | ndition was it supposed to to | reat) 1 of 1 | |
| | Hunger/nutrition | | | | |
| | 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 loc | her identifying information (The cate them) | e model, catalog, lot, seri | al, or UDI number, and the o | expiration date, if you can | |

Generated by: SYSTEM Generated on: 19-Nov-2023 22:15:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pages: 7

| | 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) | |
| S- | ction E - About the Person Wh | on Had the Problem | |
| | Person's Initials | (b)(6) | |
| | Sex | Female | |
| | Gender | Cisgender woman/girl | |
| | Please Specify Other Gender | ologonael Womanigm | |
| | Age (specify unit of time for age) | | |
| | Date of Birth | (b)(6) | |
| | Weight | 10.8 kg | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | |
| | Race (Check all that apply) | | |
| | Nace (Offect all triat apply) | American Indian or Alaska Native | |
| | | ■ Native Hawaiian or Other Pacific Islander | |
| | | ☐ Asian White | |
| | | Black or African American | |
| | | black of African American | |
| Lis | t known medical conditions (S | uch as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | | | |
| | | | |
| | | | |
| | | | |
| PΙε | ease list all allergies (such as t | o drugs, foods, pollen or others) | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | on about the person (such as smoking pregnancy alcoholuse etc.) | _ |

Generated by: SYSTEM Generated on: 19-Nov-2023 22:15:29 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-85131 | Department: CFSAN | RCT No.: RCT-1181148 | CTU Triage Date: 20-Nov-2023 | Total Pages: 7

| List all current pres | cription medications and m | edical devices being | used. | |
|----------------------------|----------------------------|------------------------|---------------------------------|---------------|
| List all salt of the prise | onputations and m | State and Hoose Bennig | | |
| | | | | |
| List all over-the-cou | unter medications and any | vitamins, minerals, su | ipplements, and herbal remedies | s being used. |
| | | | | |
| | | | | |

| tion F - About the Person Fill | ing Out This Form 1 of 1 |
|---|--------------------------|
| Primary? | Yes |
| Reporter is Patient? | |
| Title | |
| Last name | (b)(6) |
| Middle Name | |
| First name | (h)(6) |
| Number/Street | (b)(6) |
| City | |
| State/Province | |
| Country | UNITED STATES |
| ZIP or Postal code | /b\/C\ |
| Telephone number | (b)(6) |
| Email address | |
| Fax | |
| Reporter Organization | |
| Department | |
| Reporter Speciality | |
| Today's date | 19-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: 19-Nov-2023 22:15:29 Page 5 of 5



| acts | 1 pouch (71g) | 50 | % Daily Value* | %0 | %0 | %0 | 129 4% | 7% | 3 Sugars 0% | | %0 | %0 | %0 | |
|-----------------|-----------------------|--------------------|----------------|--------------|------------------|-----------------|------------|--------------|-----------------|------------|----------------|-------------|------------|------------|
| Nitrition Facts | 1 Serving per package | Amount per serving | Calories | Total Fat 0g | Saturated Fat 59 | Cholesterol Omg | Sodium Omg | Total Carbon | Total Sugars 99 | Protein 0g | Vitamin D Omcg | Calcium 4mg | Iron 0.2mg | Polassiani |

* 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

LO'F: 01023:30 EXP: 03-30-2024

Last Name

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag

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

Contact Case

First Name

| Basic Details | Basic Details | | | | | | | |
|--------------------------------|---------------|-----------------------|---------------|--|--|--|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | | | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B | | | | | |
| Priority | Routine | Routine | | | | | | |
| Override Auto Calculation Rule | No | | | | | | | |
| FDA Received Date | 19-Nov-2023 | CTU Received Date | 20-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 | | | | | | | |
| <u> </u> | ' | | | | | | | |

Email Address

Phone

| Reporter | | | | | | |
|-------------|---|--|---|--------|--|--|
| | b)(6) | (b)(6) | (b)(6) | (b)(6) | | |
| Section A - | About the Problem | | | | | |
| | d of problem was it? Il that apply) | Used a product incorrectly Noticed a problem with the | de effect (including new or worsening sym y which could have or led to a problem e quality of the product ning from one product maker to another ma | | | |
| Date the | problem occurred | 23-Aug-2023 | | | | |
| Serious | | Yes | | | | |
| | of the following happen? Il that apply) | Hospitalization - admitted Required help to prevent p Disability or health probler Birth defect Life-threatening Death Other serious/important m | permanent harm | | | |
| | rious/important medical Please Describe Below) | | | | | |

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

My daughter, (b)(6) (now 15.5 month old), was gifted approximately 6 WanaBana apple cinnamon fruit puree pouches on 08/05/2023. She consumed these over the next few weeks. At her 12-month well child check on 08/23/2023, she had her blood lead level checked. Her first toe prick (capillary) BLL result was 6.2 ug/dL, and it was confirmed by a second toe prick on the same day. To verify accuracy, she had a repeat BLL done by venous draw on 08/24/2023, with a result of 6.4 ug/dL. We live in a house built in 1952, so we assume it was an issue with our home. Our water testing came back negative for lead. Our paint testing came back with few areas of concern (and most did not have deteriorating paint prior to testing). We assumed the lead must have been present in some sort of baby food, or baby toy, as my husband and my own BLL tests came back negative as well. Everything clicked when we saw the recall alert for WanaBana apple cinnamon fruit puree pouches with our local news station. Luckily, our daughter seemed asymptomatic during this period of time and we only had a few of these pouches in our home. Without changing anything, home- or diet-wise, (other than no longer eating these pouches) our daughter's blood lead level has started to decrease. As of 10/30/2023, her blood lead level has dropped to 2.2 ug/dL.

Relevant Test/Laboratory Data

1 of 3

Generated by: SYSTEM Generated on: 20-Nov-2023 00:15:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pag

es: 5

| | Test Name | LEAD, BLOOD (PEDS) CA PILLARY (IN-HOUSE) | Test Date | 23-Aug-2023 |
|------|---|---|---------------------|------------------------------|
| | Test Result | 6.2 | Test Unit | MICROGRAMS PER DEC ILITRE |
| | Low Test Range | 0.0 ug/dL | High Test Range | 3.4 ug/dL |
| | More Information Available? | | | |
| Re | elevant Test/Laboratory Data | | | 2 of 3 |
| | Test Name | LEAD, BLOOD (PEDS) VE NOUS | Test Date | 24-Aug-2023 |
| | Test Result | 6.4 | Test Unit | MICROGRAMS PER DEC ILITRE |
| | Low Test Range | 0.0 ug/dL | High Test Range | 3.4 ug/dL |
| | More Information Available? | | | |
| Re | elevant Test/Laboratory Data | | | 3 of 3 |
| | Test Name | LEAD, BLOOD (PEDS) VE NOUS | Test Date | 30-Oct-2023 |
| | Test Result | 2.2 | Test Unit | MICROGRAMS PER DEC ILITRE |
| | Low Test Range | 0.0 ug/dL | High Test Range | 3.4 ug/dL |
| | More Information Available? | | | |
| Δc | lditional Comments | | | |
| , (| ditional Comments | | | |
| 7 10 | ditional Comments | | | |
| | ection B - Product Availability | | | |
| | ection B - Product Availability Do you still have the product in | No | | |
| | ection B - Product Availability | No No | | |
| Se | 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 | | | 1 of 1 |
| Se | 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 including a picture) | | | 1 of 1 |
| Se | 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 including a picture) ection C - About the Products | No | | 1 of 1 |
| Se | 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 including a picture) ection C - About the Products Suspect | No Yes | | 1 of 1 |
| Se | 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 including a picture) action C - About the Products Suspect Primary? | Yes Yes | | 1 of 1 |
| Se | 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 including a picture) ection C - About the Products Suspect Primary? Type | Yes Yes Drug/Biologic Food/Medical food WanaBana apple cinnamon | fruit puree pouches | 1 of 1 |
| Se | 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 including a picture) ection C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many | Yes Yes Drug/Biologic Food/Medical food | fruit puree pouches | 1 of 1 |

Generated by: SYSTEM Generated on: 20-Nov-2023 00:15:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pages: 5

| | | 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 | 05-Aug-2023 | | , | |
| | Date the person stopped taking or using the product | 01-Sep-2023 | | | |
| | Date the person reduced dose of the product | | | | |
| | Give best estimate of duration | | | | |
| | Is therapy still on-going? | | | | |
| WI | hy was the person using the pr | oduct? (such as what co | ndition was it supposed | d to treat) 1 of 1 | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Returned to Manufacturer On | | | | |
| | | | | | |
| Se | ection D - About the Medical De | evice | | | <u> </u> |
| | Name of medical device | | | | |
| | Name of the company that makes the medical device | | | | |
| Ot | | 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 | | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 00:15:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-85133 | Department: CFSAN | RCT No.: RCT-1181150 | CTU Triage Date: 20-Nov-2023 | Total Pages: 5

| Expiration date | | |
|--|--|---|
| Was someone operating the | | |
| medical device when the problem occurred? | | |
| For implanted medical devices (| DNLY (such as pacemakers, breast implants, etc.) | |
| Date the implant was put in | Date the implant was taken out (If | |
| Date the implant was put in | relevant) | |
| Section E - About the Person Wh | no Had the Problem | i |
| • | (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 | | |
| 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 | |
| I | Black of Afficial Afficial | |
| | | |
| | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| List known medical conditions (S | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagiod | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagion | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagiod | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagion | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagion | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagion Please list all allergies (such as t None known. | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagiod Please list all allergies (such as t None known. List any other important informat | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) | |
| Elevated blood lead level. Plagiod Please list all allergies (such as t None known. List any other important informat | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| Elevated blood lead level. Plagiod Please list all allergies (such as to a lead to be a lead to | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| Elevated blood lead level. Plagiod Please list all allergies (such as to a lead to be a lead to | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| Elevated blood lead level. Plagiod Please list all allergies (such as to a lead to be a lead to | Such as diabetes, high blood pressure, cancer, heart disease, or others) cephaly. to drugs, foods, pollen or others) ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |

Generated by: SYSTEM Generated on: 20-Nov-2023 00:15:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag

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

| Basic Details | (GMT-05:00) time zone | | | | |
|---|--|-----------------------|--------------|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500 | | |
| Priority | Routine | | | | |
| Override Auto Calculation Rule | No | | | | |
| FDA Received Date | 20-Nov-2023 | CTU Received Date | 20-Nov-2023 | | |
| CTU Triage Date | | CTU Data Entry Date | | | |
| Report Type | Spontaneous | Report Classification | Drug | | |
| Assign To | User | | | | |
| Jser/Group | | | | | |
| Forward to Department | | | | | |
| Case Priority | Direct | | | | |
| Contact Case First Name Reporter (b)(6) | Last Name (b)(6) | Email Address (b)(6) | Phone (b)(6) | | |
| A. PATIENT INFORMATION | | \ | | | |
| Patient Identifier (In Confidence | (b)(6) | | | | |
| Age | | | | | |
| Date of Birth | (b)(6) | | | | |
| Sex | Female Not selected | | | | |
| Gender | | | | | |
| Please Specify Other Gender | | | | | |
| Weight | Not Hispanic/Latino | | | | |
| Ethnicity (Check single best answer) | | | | | |
| Race (Check all that apply) | Asian American Indian or Alas Black or African America White Native Hawaiian or Othe | an | | | |
| 3. ADVERSE EVENT, PRODU | CT PROBLEM | | | | |
| Type of Report (check all that apply) | Adverse Event Product Use/Medication Product Problem (e.g., | | | | |
| Serious | No | | | | |
| Outcome Attributed to Adverse Event (Check all that apply) | Death Life Threatening Hospitalization (initial or Other Serious or Import | ant Medical Events | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 16:50:22 Page 1 of 4

CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | | Congenital Anomaly/Birth Defects | | | | |
|----------|--|----------------------------------|---------------------------------------|--------------------------|---|--|
| | | | nt Permanent Impairment/Damage | | | |
| | Date of Death | | | | | |
| | Date of Event | 13-Oct-2023 | | | | |
| | Date of this Report | 20-Nov-2023 | | | | |
| De | escribe Event, Problem or Prod | luct Use Error | | | | |
| | Describe Event, Problem, or Prod | | | | | |
| | pouches from April 2023 through testing was done 10/13/2023 and | | | rree. Verious blood lead | | |
| | | | | | | |
| | | | | | | |
| Re | elevant Test/Laboratory Data | | | 1 of 1 | | |
| | Test Name | VENOUS BLOOD LEAD L EVEL | Test Date | 13-Oct-2023 | | |
| | Test Result | 11.3 | Test Unit | MICROGRAMS PER DEC | | |
| | Low Test Range | 0 | High Test Range | 3.4 | | |
| | More Information Available? | | | | _ | |
| Ad | Iditional Comments | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Ot | her Relevant History, Including | Preexisting Medical Con | ditions | | | |
| Οι | Ther Trefevant History, including | The existing Medical Con | iditions | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | _ | |
| C. | PRODUCT AVAILABILITY | | | | | |
| | Product Available for Evaluation? (Do not send product to FDA) | No | | | | |
| | Returned to Manufacturer on | | | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | No | | | | |
| D | PRODUCT(S) | | | 1 of 1 | _ | |
| <u>ر</u> | Suspect | Yes | | 1 01 1 | | |
| | Primary? | Yes | | | _ | |
| | Туре | Drug/Biologic | | | _ | |
| | This report involves: | Food/Medical food | | | _ | |
| Na | ame,Strength,Manufacturer/Co | | abel) | | | |
| | Product Name | Wana Bana Apple Cinnamo | · · · · · · · · · · · · · · · · · · · | | | |
| | Strength | rr | If Other | | _ | |
| | Manufacturer/Compounder | Wana Bana | | | _ | |

Generated by: SYSTEM Generated on: 20-Nov-2023 16:50:22 Page 2 of 4

CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | NDC# or Unique ID | | | | |
|----|--|--|----------|--------|--|
| | Product Type(check all that | Отс | | | |
| | apply) | Compounded | | | |
| | | Generic | | | |
| | | Biosimilar | | | |
| | Event Abated After Use Stopped | | | | |
| L | or Dose Reduced? | | | | |
| | Event Reappeared after Reintroduction? | | | | |
| Dr | rug Therapy | | | 1 of 1 | |
| | Dose or Amount | 180 G gram(s) | If Other | | |
| | Frequency | Daily | If Other | | |
| | Route | Oral | If Other | | |
| | Dosage Form | | | J. | |
| | Start | | | - | |
| | Stop | | | | |
| | Dose Reduced | | | | |
| | Therapy Duration | | If Other | | |
| | Is therapy still on-going? | | | J | |
| | Lot Number | | | | |
| | Expiration Date | | | | |
| Di | agnosis for Use (indication) | | | 1 of 1 | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | OLIODEOT MEDIOAL DELVIO | | | | |
| E. | SUSPECT MEDICAL DEVICE | | | | |
| | Brand Name | | | | |
| | Common Device Name | | | | |
| _ | Procode | | | | |
| _ | Manufacturer Name | | | | |
| L | City | | | | |
| | State | | | | |
| | Model # | | | | |
| | Lot # | | | | |
| | Catalog # | | | | |
| | Expiration Date | | | | |
| | Serial # | | | | |
| | Unique Identifier (UDI)# | | | | |
| | | | | | |
| | Operator of Device | Health Professional | | | |
| | Operator of Device | Health Professional Patient/Consumer | | | |
| | Operator of Device | Health Professional Patient/Consumer Other | | | |
| | Operator of Device Other | Patient/Consumer | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 16:50:22 Page 3 of 4

CTU No.: FDA-CDER-CTU-2023-85444 | Department: CFSAN | RCT No.: RCT-1181405 | CTU Triage Date: 21-Nov-2023 | Total Pages 4

| | 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 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| IG. | REPORTER | | | 1 of 1 | |
| | Primary? | Yes | | | Т |
| | Reporter is Patient? | | | | |
| | Title | | | | |
| | Last Name | (b)(6) | | | |
| | Middle Name | | | | |
| | First Name | (b)(C) | | | |
| | Address | (b)(6) | | | |
| | City | () () | | | |
| | State/Province/Region | | | | |
| | Country | UNITED STATES | If Other | | |
| | ZIP/Postal Code | /L-\/C | | | |
| | Phone | | | | |
| | Email | $(\mathcal{O})(\mathcal{O})$ | | | |
| | Fax | | | | |
| | Reporter Organization | | | | |
| | Department | | | | |
| | Reporter Speciality | | | | |
| | Health Professional? | Yes | | | |
| | Occupation | Nurse | If Other | | |
| | Also Reported to | Manufacturer/Com User Facility Distributor/Importe | | | |
| | If you do NOT want your identity disclosed to the manufacturer | No | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 16:50:22 Page 4 of 4

CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | MT-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 | 20-Nov-2023 | CTU Received Date | 20-Nov-2023 |
| CTU Triage Date | | CTU Data Entry Date | |
| Report Type | Spontaneous | Report Classification | Drug |
| Assign To | User | | |
| User/Group | | | |
| Forward to Department | Ø | | |
| Case Priority | Direct | | |
| | I | | |
| Contact | | | |
| Case First Name | Last Name | Email Address | Phone |
| Reporter (b)(6) | (b)(6) | (12)(0) | /b\/C\ |
| (b)(6) | (b)(6) | (b)(6) | (b)(6) |
| Section A - About the Problem | | | |
| | | | |
| What kind of problem was it? | Ware burt or had a have | d side offect (including new or wereening sympton | ma) |
| (Check all that apply) | | d side effect (including new or worsening sympton | ms) |
| | Used a product incorre | ectly which could have or led to a problem | ns) |
| | Used a product incorre | ectly which could have or led to a problem the quality of the product | |
| | Used a product incorre | ectly which could have or led to a problem | |
| (Check all that apply) | Used a product incorre Noticed a problem with | ectly which could have or led to a problem the quality of the product | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 | ectly which could have or led to a problem the quality of the product itching from one product maker to another maker | |
| (Check all that apply) Date the problem occurred Serious | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit | ectly which could have or led to a problem the quality of the product itching from one product maker to another maker ted or stayed longer | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit | ectly which could have or led to a problem in the quality of the product itching from one product maker to another maker ted or stayed longer ent permanent harm | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit Required help to preve | ectly which could have or led to a problem in the quality of the product itching from one product maker to another maker ted or stayed longer ent permanent harm | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit | ectly which could have or led to a problem in the quality of the product itching from one product maker to another maker ted or stayed longer ent permanent harm | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit Required help to preve | ectly which could have or led to a problem in the quality of the product itching from one product maker to another maker ted or stayed longer ent permanent harm | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? | Used a product incorre Noticed a problem with Had problems after sw 13-Oct-2023 No Hospitalization - admit Required help to preve Disability or health pro Birth defect Life-threatening Death | ectly which could have or led to a problem in the quality of the product itching from one product maker to another maker ted or stayed longer ent permanent harm | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) | Used a product incorre Noticed a problem with Had problems after sw. 13-Oct-2023 No Hospitalization - admit Required help to preven Disability or health pro Birth defect Life-threatening Death Other serious/importar | ectly which could have or led to a problem In the quality of the product In the quality of the product maker to another maker | |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) 4.Tell us what happened and howany additional documents if necessary additional decuments if necessary and the serious ser | Used a product incorred Noticed a problem with Had problems after sw. 13-Oct-2023 No Hospitalization - admit Required help to preve Disability or health problems Birth defect Life-threatening Death Other serious/importar | ectly which could have or led to a problem in the quality of the product vitching from one product maker to another maker ited or stayed longer ent permanent harm blem | DA may reach out to you for |
| (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) 4. Tell us what happened and howany additional documents if nece | Used a product incorred Noticed a problem with Had problems after sw. 13-Oct-2023 No Hospitalization - admit Required help to preve Disability or health problems Birth defect Life-threatening Death Other serious/importar | ectly which could have or led to a problem on the quality of the product vitching from one product maker to another maker ted or stayed longer ent permanent harm blem | DA may reach out to you for |

| F | Relevant Test/Laboratory Data | | | 1 of 6 | |
|---|-------------------------------|-------------|-----------------|------------------------------|--|
| | Test Name | LEAD,VENOUS | Test Date | 06-Nov-2023 | |
| | Test Result | 10.4 | Test Unit | MILLIGRAMS PER DECIL ITRE | |
| | Low Test Range | | High Test Range | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 15:20:22 Page 1 of 5 CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag

es: 5

| More Yn1brmation Available? | | | |
|--|-------------------|-----------------|----------------------------|
| elevant Test/Laboratory Data | | | 2 011 |
| Test Name | LEAD:6ENOUS | Test Date | 14-Nov-2023 |
| Test Result | 7 | Test Unit | MYLYGRAMS PER DECY YTRE |
| Lof Test Range | | High Test Range | |
| More Yn 15rmation Available? | | | |
| elevant Test/Laboratory Data | | | 3 o1l |
| Test Name | HEMATOCRY | Test Date | 14-Nov-2023 |
| Test Result | 28v6 | Test Unit | PERCENT |
| Lof Test Range | | High Test Range | |
| More Yn¹brmation Available? | | | |
| elevant Test/Laboratory Data | | | 4 011 |
| Test Name | HEMATOCRY | Test Date | 03-Nov-2023 |
| Test Result | 32w | Test Unit | PERCENT |
| Lof Test Range | | High Test Range | |
| More Yn1brmation Available? | | | |
| elevant Test/Laboratory Data | | | 5 011 |
| Test Name | HEMOGLOB W | Test Date | 03-Nov-2023 |
| Test Result | 11 | Test Unit | GRAMS PER DECYLYTER |
| Lof Test Range | | High Test Range | |
| More Yn¹brmation Available? | | | |
| elevant Test/Laboratory Data | | | l o1l |
| Test Name | HEMOGLOB'W | Test Date | 14-Nov-2023 |
| Test Result | 10v2 | Test Unit | GRAMS PER DECYLYTER |
| Lof Test Range | | High Test Range | |
| More Yn¹brmation Available? | | | |
| dditional Comments | | | |
| | | | |
| ection B - Product Availability | | | |
| Do you still have the product in case f e need to evaluate it? | No | | |
| Do you have a picture o1the product? (check yes i1you are | No | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 15:20:22 Page 2 o15

1 011

Section C - About the Products

CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag

| Suspect | Yes | | | |
|---|---|--------------------------------|-------------|--|
| Primary? | Yes | | | |
| Туре | Drug/Biologic | | | |
| This report is about | Food/Medical 1ood | | | |
| Name o1the product as it appears on the bo4xbottlex or package (Yiclude as many names as you see) | Wana bana cinnamon apple | e puree 3 pack | | |
| Name o1the company that makes (or compounds) the product | Wana bana | | | |
| Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar | or an Outsourcing Facility | | |
| Strength | | YOther | | |
| NDC number | | | J | |
| Did the problem stop a1er the person reduced the dose or stopped taking or using the product? | | | | |
| Did the problem return i1the person started taking or using the product again? | | | | |
| Drug Therapy | | | 1 011 | |
| E4piration date | | | | |
| Lot number | | | | |
| Dosage Form | | | | |
| Vuantity | | MOther | | |
| Frequency | | MOther | | |
| Hof f as it taken or used | Oral | MOther | | |
| Date the person 1rst started taking or using the product | 25-Sep-2023 | | | |
| Date the person stopped taking or using the product | 20-Oct-2023 | | | |
| Date the person reduced dose o1 the product | | | | |
| Give best estimate o1duration | | | | |
| Ys therapy still on-going? | | | | |
| Why f as the person using the pr | oduct? (such as f hat cor | ndition t as it supposed to ti | reat) 1 o11 | |
| | | | | |
| Returned to Manu1acturer On | | | <u> </u> | |
| Tretumed to Manu acturer Off | | | | |
| Section D - About the Medical De | evice | | | |
| Name o1medical device | | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 15:20:22 Page 3 o15

CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | Name of the company that makes the medical device | | | | |
|-----------|---|---------------------------|-------|--|----------|
| Ot loc | her identifying information (The cate them) | e model, catalog, lot, | seria | al, or UDI number, and the expiration date, if you can | |
| | · | | | | П |
| | | | | | |
| | | | | | |
| | Model Number | | | | \vdash |
| | Catalog Number | | | | |
| | Lot Number | | | | |
| | Serial Number | | | | |
| | UDDI Number | | | | |
| | Expiration date | | | | |
| | Was someone operating the medical device when the problem occurred? | 1 | | | |
| lFo | r implanted medical devices C | NLY (such as pacem | ake | 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 | | | |
| | | (b)(6) | | | |
| | Sex | Female | | | |
| | Gender | Cisgender woman/girl | | | \vdash |
| | Please Specify Other Gender | | | | \vdash |
| | Age (specify unit of time for age) | | | | \vdash |
| | Date of Birth | (b)(6) | | | |
| | Weight | 7.65 kg | | | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | | | \Box |
| | Race (Check all that apply) | American Indian or Alask | a Nat | ve | Т |
| | | Native Hawaiian or Other | | | |
| | | Asian | | | |
| | | White | | | |
| | | Black or African American | n | | |
| Lis | t known medical conditions (S | Such as diabetes, high | blo | od pressure, cancer, heart disease, or others) | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Ple | ease list all allergies (such as t | to drugs, foods, poller | or | others) | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 15:20:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-85421 | Department: CFSAN | RCT No.: RCT-1181350 | CTU Triage Date: 21-Nov-2023 | Total Pag

| Li | st any other important inform | ation about the person (such as smoking, pregnancy, alcohol use, etc.) | |
|----------|---------------------------------|---|---|
| | | | |
| | | | |
| | | | |
| L | | | |
| Li | st all current prescription me | dications and medical devices being used. | |
| | Prescription iron supplement st | arted 11/18 | |
| | | | |
| | | | |
| | | | |
| | st all over-the-counter medic | ations and any vitamins, minerals, supplements, and herbal remedies being used. | |
| T | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| S | ection F - About the Person F | Filling Out This Form 1 of 1 | |
| Г | Primary? | Yes | |
| | Reporter is Patient? | | |
| Г | Title | | |
| | Last name | (b)(6) | |
| Г | Middle Name | | |
| | First name | (b)(6) | |
| | Number/Street | (D)(U) | |
| | City | | |
| | State/Province | | |
| | Country | UNITED STATES | |
| | ZIP or Postal code | (b)(c) | |
| | Telephone number | (b)(6) | |
| \vdash | Email address | | _ |

Generated by: SYSTEM Generated on: 20-Nov-2023 15:20:22 Page 5 of 5

20-Nov-2023

Yes

Fax

Department

Today's date

Reporter Organization

Reporter Speciality

If you do NOT want your

identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):

Did you report this problem to the company that makes the product (the manufacturer/compounder)?

CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag

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

| Ba | asic Details | | | | | |
|----------|------------------------------------|--|-----------------------|--------------|--|--|
| С | ompany Unit | CDER-CTU | Originating Account | FAERS | | |
| S | ource Medium | MWO (Drug) | Source Form Type | E2B XML 3500 | | |
| Р | riority | Routine | - | | | |
| 0 | verride Auto Calculation Rule | No | | | | |
| F | DA Received Date | 20-Nov-2023 | CTU Received Date | 20-Nov-2023 | | |
| С | TU Triage Date | | CTU Data Entry Date | | | |
| R | eport Type | Spontaneous | Report Classification | Drug | | |
| A | ssign To | User | - | , | | |
| U | ser/Group | | | | | |
| F | orward to Department | \square | | | | |
| С | ase Priority | Direct | | | | |
| | | <u> </u> | | | | |
| Co | ontact | | | | | |
| | ase First Name | Last Name | Email Address | Phone | | |
| | eporter (h)(6) | (b)(6) | /b\/C\ | (b)(6) | | |
| Ā | (b)(6) | (b)(6) | (b)(6) | (5)(0) | | |
| A. | PATIENT INFORMATION | | () () | _ | | |
| | Patient Identifier (In Confidence) | (b)(6) | | | | |
| | Age | 21 Month(s) | | | | |
| | Date of Birth | ., | | | | |
| \vdash | Sex | Male | | | | |
| \vdash | Gender | Cisgender man/boy | | | | |
| | Please Specify Other Gender | | | | | |
| | Weight | 10.2 kg | | | | |
| | Ethnicity (Check single best | Hispanic/Latino | | | | |
| | answer) | <u> </u> | | | | |
| | Race (Check all that apply) | Asian | | | | |
| | | American Indian or Alaska | a Native | | | |
| | | Black or African American | | | | |
| | | White | | | | |
| | | Native Hawaiian or Other | Pacific Islander | | | |
| B. | ADVERSE EVENT, PRODUC | T PROBLEM | | | | |
| | Type of Report (check all that | Adverse Event | | | | |
| | apply) | Product Use/Medication E | rror | | | |
| | | Product Problem (e.g., def | fects/malfunctions) | | | |
| | | Problem with Different Manufacturer of Same Medicine | | | | |
| | Serious | Yes | | | | |
| | Outcome Attributed to Adverse | Death | | | | |
| | Event (Check all that apply) | Life Threatening | | | | |
| | | Hospitalization (initial or pr | rolonged) | | | |
| | | Other Serious or Important | t Medical Events | | | |
| | | Disability or Permanent Da | amage | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 14:45:26 Page 1 of 4

CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | . — | | |
|--|----------------------------|---------------------------------------|-----------------------------|
| | Congenital Anomaly/Birth | Defects | |
| | Required Intervention to F | Prevent Permanent Impairment/Damage | |
| Date of Death | | | |
| Date of Event | 15-Nov-2023 | | |
| Date of this Report | 20-Nov-2023 | | |
| Describe Event, Problem or Prod | duct Use Error | | |
| Describe Event, Problem, or Proc part of the recall. he has an eleva | | pple sauce with cinnamon that w | as made by wanabana and was |
| Relevant Test/Laboratory Data | | | 1 of 1 |
| Test Name | LEAD | Test Date | 15-Nov-2023 |
| Test Result | | Test Unit | MICDOCDAMO DED DEO |
| | 10.9 | | MICROGRAMS PER DEC |
| Low Test Range | 0 | High Test Range | 3.4 |
| More Information Available? | | | |
| dditional Comments | | | |
| Other Relevant History, Including | g Preexisting Medical (| Conditions | |
| C. PRODUCT AVAILABILITY | | | |
| Product Available for Evaluation? (Do not send product to FDA) | No | | |
| Returned to Manufacturer on | | | |
| Do you have a picture of the product? (check yes if you are including a picture) | No | | |
| . PRODUCT(S) | | | 1 of 1 |
| Suspect | Yes | | |
| Primary? | Yes | | |
| Туре | Drug/Biologic | | |
| This report involves: | Food/Medical food | | |
| ame,Strength,Manufacturer/Co | | uct label) | |
| Product Name | wanabana applesauce | · · · · · · · · · · · · · · · · · · · | |
| Strength | | If Other | |

Generated by: SYSTEM Generated on: 20-Nov-2023 14:45:26 Page 2 of 4

Manufacturer/Compounder

CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pag

| | | | | · | т — |
|-----|---|--------------------------------------|----------|--------|-----|
| | NDC# or Unique ID | | | | |
| | Product Type(check all that | Отс | | | |
| | apply) | Compounded | | | |
| | | Generic | | | |
| | | Biosimilar | | | |
| | Event Abated After Use Stopped or Dose Reduced? | Doesn't Apply | | | |
| | Event Reappeared after Reintroduction ? | Doesn't Apply | | | |
| Dr | 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 | | | | |
| | Expiration Date | | | | |
| Dia | agnosis for Use (indication) | | | 1 of 1 | |
| Dia | | | | 1 of 1 | |
| Dia | | | | 1 of 1 | |
| Dia | | | | 1 of 1 | |
| Dia | | | | 1 of 1 | |
| | agnosis for Use (indication) | | | 1 of 1 | |
| | agnosis for Use (indication) SUSPECT MEDICAL DEVICE | | | 1 of 1 | |
| | agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name | | | 1 of 1 | |
| | agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # | | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)# | Health Professional Patient/Consumer | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)# | Health Professional | | 1 of 1 | |
| | SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)# | Health Professional Patient/Consumer | | 1 of 1 | |

Generated by: SYSTEM Generated on: 20-Nov-2023 14:45:26 Page 3 of 4

CTU No.: FDA-CDER-CTU-2023-85414 | Department: CFSAN | RCT No.: RCT-1181331 | CTU Triage Date: 21-Nov-2023 | Total Pages: 4

| | 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 PRODUC | CTS | | | |
| | CONCOMITANT MEDICAL PROD | UCT DESCRIPTION | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| G. | REPORTER | | | | 1 of 1 | |
| | Primary? | Yes | | | | |
| | Reporter is Patient? | | | | | |
| | Title | | | | | |
| | Last Name (| b)(6) | | | | |
| | Middle Name | | | | | |
| | First Name | (b)(6) | | | | |
| | Address | | | | | |
| | City | | | | | |
| | State/Province/Region | | | | | |
| | Country | UNITED STATES | | If Other | | |
| | ZIP/Postal Code | /b\/(| 7/ | | | |
| | Phone | $(\mathbf{D})(\mathbf{C})$ | | | | |
| | Email | (.0)(| | | | |
| | Fax | | | | | |
| | Reporter Organization | | | | | |
| | Department | | | | | |
| | Reporter Speciality | | | | | |
| | Health Professional? | Yes | | | | |
| | Occupation | Physician | | If Other | | |
| | Also Reported to | Manufacturer/C User Facility Distributor/Impo | | er | | |
| | If you do NOT want your identity disclosed to the manufacturer | No | | | | |

Generated by: SYSTEM Generated on: 20-Nov-2023 14:45:26 Page 4 of 4

CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag

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

| All dates displayed in the report are in EST(G | MT-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 | 22-Nov-2023 | CTU Received Date | 22-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 | | | | | | |
| | I. | | | | | | |
| Contact | | | | | | | |
| Case First Name | Last Name | Email Address | Phone | | | | |
| Reporter (b)(6) | (b)(6) | (b)(6) | (b)(6) | | | | |
| | (D)(O) | (6)(6) | (5)(5) | | | | |
| Section A - About the Problem | | | | | | | |
| What kind of problem was it? (Check all that apply) | Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product | | | | | | |
| | Had problems after switching from one product maker to another maker | | | | | | |
| Date the problem occurred | 31-Oct-2023 | | | | | | |
| Serious | Yes | 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 perious/immediant mod | lical incident(Please Describe Below) | | | | | |
| Other serious/important medical | Other serious/important med | ical incident(Flease Describe Below) | | | | | |
| incident(Please Describe Below) | | | | | | | |
| 4.Tell us what happened and how any additional documents if nece | w it happened (Include a ssary) | as many details as possible FD/ | A may reach out to you for | | | | |
| | | vithin 2 weeks before I was aware of eating, and just felt horrible. I had hi | | | | | |

| Relevant Test/Laboratory Data 1 | | | | | |
|---------------------------------|----------------|-----------|-----------------|-------------|--|
| | Test Name | LEAD TEST | Test Date | 31-Oct-2023 | |
| | Test Result | 12.2 | Test Unit | UNKNOWN | |
| | Low Test Range | | High Test Range | | |

Generated by: SYSTEM Generated on: 22-Nov-2023 15:15:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag

es: 6

| | More Information Available? | | | | | | |
|----|---|--|--|-------|------------|--|--|
| Ad | ditional Comments | | | | | | |
| | Health department came and we haccess to any lead paint. | nave no other source of | ve no other source of contamination. We live in a house built in 2009, he doesn't have | | | | |
| Se | ection B - Product Availability | | | | | | |
| | Do you still have the product in case we need to evaluate it? | Yes | | | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | Yes | | | | | |
| Se | ection C - About the Products | | | | 1 of 1 | | |
| | Suspect | Yes | | | | | |
| | Primary? | Yes | | | | | |
| | Туре | Drug/Biologic | | | | | |
| | This report is about | Food/Medical food | | | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wanabana Apple cinn | namon applesauce | pouch | | | |
| | Name of the company that makes (or compounds) the product | Wanabana | | | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Phan 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? Did the problem return if the | No | | | | | |
| | person started taking or using the product again? | Doesn't Apply | | | | | |
| Dr | ug Therapy | | | | 1 of 1 | | |
| | Expiration date | 23-Jun-2024 | | | | | |
| | Lot number | 0402323 | | | | | |
| | Dosage Form | | | | | | |
| | Quantity | Other | If Other | | 14 Pouches | | |
| | Frequency | Twice a day | If Other | | | | |
| | How was it taken or used | Oral | If Other | | | | |
| | Date the person first started taking or using the product | 15-Oct-2023 | | | | | |
| | Date the person stopped taking or using the product | 31-Oct-2023 | | | | | |

Generated by: SYSTEM Generated on: 22-Nov-2023 15:15:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag

| Date the person reduced dose of the product | 31-Oct-2023 | | | |
|---|-------------------------------|--|------------------------|---|
| Give best estimate of duration | | | | |
| Is therapy still on-going? | Yes | | | |
| Why was the person using the pr | roduct? (such as what cor | ndition was it supposed to treat) | 1 of 1 | |
| Food he likes to eat | | | | |
| Returned to Manufacturer On | | | | |
| Section D - About the Medical De | evice | | | |
| Name of medical device | | | | |
| Name of the company that | | | | |
| makes the medical device Other identifying information (The | | -l l D 4b | stien dete if very sen | |
| locate them) | e model, catalog, lot, seria | al, or ODI number, and the expira | ation 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? | ı | | | |
| For implanted medical devices C | NLY (such as pacemake | rs, breast implants, etc.) | | |
| Date the implant was put in | | Date the implant was taken out (If relevant) | | |
| Section E - About the Person Wh | no Had the Problem | | | |
| Person's Initials | (b)(6) | | | |
| Sex | Male | | | _ |
| Gender | Cisgender man/boy | | | |
| Please Specify Other Gender | | | | |
| Age (specify unit of time for age) | | | | |
| Date of Birth | (b)(6) | | | |
| Weight | 15.75 kg | | | |
| Ethnicity (Choose only one) | Not Hispanic/Latino | | | |
| Race (Check all that apply) | American Indian or Alaska Nat | | | |

Generated by: SYSTEM Generated on: 22-Nov-2023 15:15:23 Page 3 of 5

Asian

CTU No.: FDA-CDER-CTU-2023-86224 | Department: CFSAN | RCT No.: RCT-1182021 | CTU Triage Date: 27-Nov-2023 | Total Pag

es: 6

| | | White Black or African American | |
|----------|----------------------------------|---|---|
| Lis | t known medical conditions (S | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | Autism level 2 | | |
| | | | |
| | | | |
| | | | |
| PΙε | 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.) | |
| | Dev. Delays | | |
| | | | |
| | | | |
| | | | |
| Lis | | cations and medical devices being used. | |
| | Guanfacine | | |
| | | | |
| | | | |
| | | | |
| LIS | Polyvisol | ions and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | l diyvisoi | | |
| | | | |
| | | | |
| | | | |
| 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 | (b)(6) | |
| | Number/Street | | _ |
| \sqcup | City | | _ |
| | State/Province | LINITED CTATES | |
| | Country | UNITED STATES | |
| \vdash | ZIP or Postal code | (b)(6) | _ |
| \vdash | Telephone number | | _ |
| | Email address | | |



CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag

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

Low Test Range

| Denie Deteile | | | | | | | |
|-----------------------|---|--|---|--|-------------------------------|---|--|
| Basic Deta | | ODED OTH | 0:: | , | FAFDO | | |
| Company | | CDER-CTU | Originating Acco | | FAERS | _ | |
| Source Me | alum | MWO (Drug) | Source Form Typ | oe ———————————————————————————————————— | E2B XML 3500B | _ | |
| Priority | ota Calandatian Boda | Routine | | | | _ | |
| | uto Calculation Rule | No SAN SOOS | 07110 : 10 | | 04.11 0000 | | |
| FDA Recei | | 24-Nov-2023 | CTU Received D | | 24-Nov-2023 | | |
| CTU Triag | | _ | CTU Data Entry | | | _ | |
| Report Typ | De . | Spontaneous | Report Classifica | ation | Drug | | |
| Assign To | | User | | | | | |
| User/Grou | | | | | | _ | |
| Forward to | Department | | | | | | |
| Case Prior | ity | Direct | | | | | |
| | | | | | | | |
| Contact | | | | | | | |
| Case | First Name | Last Name | Email Add | Iress | Phone | | |
| Reporter | (b)(6) | (b)(6) | | | (b)(6) | _ | |
| | | | | | (6)(6) | | |
| | - About the Problem | | | | | | |
| | ind of problem was it? all that apply) | Were hurt or had a bad side effect (including new or worsening symptoms) | | | | | |
| (Onocik | an triat apply) | Used a product incorrectly which could have or led to a problem | | | | | |
| | | Noticed a problem with the quality of the product | | | | | |
| | | | g from one product maker to another maker | | | | |
| | e problem occurred | 19-Nov-2023 | | | | _ | |
| Serious | | Yes | | | | | |
| | of the following happen? all that apply) | Hospitalization - admitted or stayed longer | | | | | |
| (Oncor | an that apply) | Required help to prevent permanent harm | | | | | |
| | | Disability or health problem | | | | | |
| | | Birth defect | Birth defect | | | | |
| | | Life-threatening | | | | | |
| | | Death | | | | | |
| Othor | erious/important medical | Other serious/important medical incident(Please Describe Below) | | | | | |
| | t(Please Describe Below) | | | | | | |
| | vhat happened and hovenal documents if nece | | s many details as | s possible FDA | may reach out to you for | | |
| CFSAN | CAERS PHONE REPOR | T 24-NOV-2023:My name is | | | na Apple Cinamon, | | |
| | | nmediately after, I had a rea | | | | | |
| | e and itcny. I continue to ex to go about this, I believe th | kperience these symptoms a here is lead in my system. | and they are getting | worse. This produ | act is recalled, I don't know | | |
| | _ , | , -, | | | | | |
| | | | | | | _ | |
| Relevant ⁻ | Test/Laboratory Data | | | | 1 of 1 | | |
| Test Na | ame | | Test Date | | | | |
| Test Re | esult | | Test Unit | | | | |

Generated by: SYSTEM Generated on: 24-Nov-2023 13:45:25 Page 1 of 5

High Test Range

CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag

es: 5

| | More Information Available? | | | |
|----|---|--|--|--|
| Ac | Additional Comments | | | |
| | | | | |
| Se | Section 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 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 CINAMON PAUCH | | |
| | 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 | 19-Nov-2023 | | |
| | Date the person stopped taking | | | |

Generated by: SYSTEM Generated on: 24-Nov-2023 13:45:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| | 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 treat) 1 of 1 | |
| | | | |
| | Returned to Manufacturer On | | |
| Se | ection D - About the Medical De | evice | |
| | Name of medical device | , alece | |
| | Name of the company that makes the medical device | | \vdash |
| Ot | | 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 | 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 | o Had the Problem | |
| | Person's Initials | (b)(6) | Т |
| | Sex | Not selected | |
| | Gender | Not selected | |
| | Please Specify Other Gender | | |
| | Age (specify unit of time for age) | | |
| | Date of Birth | | |
| | Weight | | |
| | Ethnicity (Choose only one) | | |
| | Race (Check all that apply) | American Indian or Alaska Native | |
| | | Native Hawaiian or Other Pacific Islander | |
| | | Asian | |

Generated by: SYSTEM Generated on: 24-Nov-2023 13:45:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag

| | es: 5 | | |
|----------|--|--|---------|
| | | White Black or African American | |
| lLis | st known medical conditions (S | uch as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | | | Т |
| | | | |
| | | | |
| | | | |
| IPI | ease list all allergies (such as t | o drugs, foods, pollen or others) | |
| | | | Т |
| | | | |
| | | | |
| | | | |
| Lis | st any other important informat | on about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | | Т |
| | | | |
| | | | |
| | | | |
| | at all according to a saintian mandic | estions and modical devices being used | _ |
| | st all current prescription medic | eations and medical devices being used. | Т |
| | | | |
| | | | |
| | | | |
| | | | <u></u> |
| Lis | st all over-the-counter medicati | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | | | |
| | | | |
| | | | |
| | | | |
| 10 | | | |
| 36 | ection F - About the Person Fill Primary? | ing Out This Form 1 of 1 Yes | |
| \vdash | Reporter is Patient? | res | - |
| | Title | | + |
| | Last name | (b)(6) | + |
| | Middle Name | (b)(6) | + |
| | | (b)(6) | + |
| _ | First name | | + |
| | Number/Street | | 1 |
| | City | | 1 |
| 1 | State/Province | | 1 |

Generated by: SYSTEM Generated on: 24-Nov-2023 13:45:25 Page 4 of 5

UNITED STATES

(b)(6)

Country

ZIP or Postal code

Telephone number Email address

CTU No.: FDA-CDER-CTU-2023-86364 | Department: CFSAN | RCT No.: RCT-1182272 | CTU Triage Date: 27-Nov-2023 | Total Pag

| Fax | | |
|---|-------------|--|
| Reporter Organization | | |
| Department | | |
| Reporter Speciality | | |
| Today's date | 24-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: 24-Nov-2023 13:45:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pag

| - | yed in the report are in EST(G | MT-05:00) time zone | | |
|------------------------|--|--|--|---------------|
| Basic Deta | | | | <u> </u> |
| Company L | Jnit | CDER-CTU | Originating Account | FAERS |
| Source Medium Priority | | MWO (Drug) | Source Form Type | E2B XML 3500B |
| | | Routine | | |
| Override Au | uto Calculation Rule | No | | |
| FDA Receiv | ved Date | 25-Nov-2023 | CTU Received Date | 25-Nov-2023 |
| CTU Triage | e Date | | CTU Data Entry Date | |
| Report Type | е | Spontaneous | Report Classification | Drug |
| Assign To | | User | | |
| User/Group |) | | | |
| Forward to | Department | | | |
| Case Priori | ty | Direct | | |
| Contact | | | | |
| Case Reporter | First Name | Last Name | Email Address | Phone |
| Reporter | (b)(6) | (b)(6) | (b)(6) | (b)(6) |
| Section A - | - About the Problem | | | |
| | nd of problem was it? all that apply) | Used a product incorrectly Noticed a problem with the | le effect (including new or worsening sympto which could have or led to a problem quality of the product ing from one product maker to another make | |
| Date the | e problem occurred | 15-Oct-2023 | product mans, to another man | |
| Serious | | No | | |
| | of the following happen? | Hospitalization - admitted of | or stayed longer | |

| 1 | Required help to prevent permanent harm | |
|---|--|--|
| | Disability or health problem | |
| | Birth defect | |
| | Life-threatening | |
| | Death | |
| | Other serious/important medical incident(Please Describe Below) | |
| | | |
| | Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for additional documents if necessary) | |
| | | |
| | ny additional documents if necessary) | |
| | ny additional documents if necessary) | |

(Check all that apply)

| ĮR | elevant Test/Laboratory Data | | | 1 of 1 | |
|----|------------------------------|-------------------|-----------------|-------------|--|
| | Test Name | LEAD | Test Date | 10-Nov-2023 | |
| | Test Result | Slightly elevated | Test Unit | | |
| | Low Test Range | | High Test Range | | |
| | More Information Available? | | | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 08:45:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pag

es: 5

| Ad | ditional Comments | | | | |
|-----|---|---|---------------------------------|------------------------------------|--|
| | I don't have a copy of the test, pre and to feed her calcium and retest | | e but don't remember anything e | except that it's slightly elevated | |
| 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) | Cinnamon Applesauce | | | |
| | Name of the company that makes (or compounds) the product | Wana Bana | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar | or an Outsourcing Facility | | |
| | Strength | | If Other | | |
| | NDC number | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | Yes | | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | | | |
| Dru | ug Therapy | | | 1 of 1 | |
| | Expiration date | | | | |
| | Lot number | | | | |
| | Dosage Form | | | | |
| | Quantity | Other | If Other | 3 Pouch | |
| | Frequency | As needed | 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 | | | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 08:45:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| | Give best estimate of duration | 3 Month | |
|-----|--|---|--|
| | Is therapy still on-going? | | |
| W | | oduct? (such as what condition was it supposed to treat) 1 of 1 | |
| | Food | | |
| | | | |
| | | | |
| | | | |
| | Returned to Manufacturer On | | |
| Se | ection D - About the Medical De | evice | |
| | Name of medical device | | |
| | Name of the company that | | |
| 01 | makes the medical device | | |
| 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 | Female | |
| | Gender | Cisgender woman/girl | |
| | Please Specify Other Gender | | |
| | Age (specify unit of time for age) | | |
| | Date of Birth | (b)(6) | |
| | Weight | 15.75 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 | |
| ı l | | Black or African American | |

Generated by: SYSTEM Generated on: 25-Nov-2023 08:45:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| Il ist known modical so | aditions (Such as dishotos hi | gh blood pressure, cancer, heart disease, or others) | |
|---------------------------|---------------------------------------|--|---|
| Genetic connective tis | | gri blood pressure, caricer, rieart disease, or others) | |
| Genetic connective its | sue disorder | | |
| | | | |
| | | | |
| | | | |
| Please list all allergies | (such as to drugs, foods, poll | en or others) | |
| None | | | |
| | | | |
| | | | |
| | | | |
| List anv other importar | nt information about the perso | n (such as smoking, pregnancy, alcohol use, etc.) | |
| She ate a *lot* of the | · · · · · · · · · · · · · · · · · · · | 3, 1-3 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | tion medications and medical | devices being used. | |
| Albuterol | | | |
| | | | |
| | | | |
| | | | |
| List all over-the-counte | r medications and any vitami | ns, minerals, supplements, and herbal remedies being used. | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | _ |
| Section F - About the I | Person Filling Out This Form | 1 of 1 | |
| Primary? | Yes | | |
| Reporter is Patient? | | | |
| Title | | | |
| Last name | (b)(6) | | |
| Middle Name | | | |
| First name | /L\/C | \ | _ |
| Number/Street | -(n)(n | | |
| City | (b)(6 | 1 | |
| State/Province | | | |
| Country | UNITED STATES | | _ |
| ZIP or Postal code | | | _ |
| Telephone number | - (h) (6) | | |
| | =(b)(6) | ·) | |
| Email address | \ /\ | | _ |
| Fax | | | |
| Reporter Organization | 1 | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 08:45:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-86475 | Department: CFSAN | RCT No.: RCT-1182375 | CTU Triage Date: 27-Nov-2023 | Total Pag

| Department | | |
|---|-------------|--|
| Reporter Speciality | | |
| Today's date | 25-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: 25-Nov-2023 08:45:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pag

| All dates displayed in the report are in EST(G | MT-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 | 25-Nov-2023 | CTU Received Date | 25-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 | | |
| ☑ (p)(e) | (b)(6) | (b)(6) | (b)(6) |
| Section A - About the Problem | ' | | |
| What kind of problem was it? | | | |
| (Check all that apply) | Used a product incorrectly Noticed a problem with the | de effect (including new or worsening sympto y which could have or led to a problem e quality of the product ning from one product maker to another make | |
| | Used a product incorrectly Noticed a problem with the | y which could have or led to a problem e quality of the product | |
| (Check all that apply) | Used a product incorrectly Noticed a problem with th Had problems after switch | y which could have or led to a problem e quality of the product | |
| (Check all that apply) Date the problem occurred | Used a product incorrectly Noticed a problem with th Had problems after switch 27-Oct-2023 | y which could have or led to a problem e quality of the product ning from one product maker to another make or stayed longer permanent harm | |

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

child tested for elevated lead levels related to wanabana fruit pouches

| Relevant Test/Laboratory Data 1 of | | | | | |
|------------------------------------|----------------|------------|-----------------|--------------------|--|
| | Test Name | LEAD LEVEL | Test Date | 27-Oct-2023 | |
| | Test Result | 6.8 | Test Unit | MICROGRAMS PER DEC | |
| | Low Test Range | 0 | High Test Range | 3.5 | |

Page 1 of 5 Generated by: SYSTEM Generated on: 25-Nov-2023 13:15:29

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pag

| _ | _ | |
|---|---|----|
| е | S | o. |

| | More Information Available? | | | | | | |
|----|--|--|-----------------|--------------------|--|--|--|
| Re | Relevant Test/Laboratory Data 2 of 2 | | | | | | |
| | Test Name | LEAD LEVEL | Test Date | 17-Nov-2023 | | | |
| | Test Result | 4.3 | Test Unit | MICROGRAMS PER DEC | | | |
| | Low Test Range | 0 | High Test Range | 3.5 | | | |
| | More Information Available? | | | | | | |
| Ad | ditional Comments | | | | | | |
| | lead level improved with removal of WanaBana pouches | | | | | | |
| 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 | No | | | | |
| Se | ction C - About the Products | | | 1 of 1 | | | |
| | Suspect | Yes | | | | | |
| | Primary? | Yes | Yes | | | | |
| | Туре | Drug/Biologic | 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) Name of the company that makes (or compounds) the product | Wana Bana Apple Cinnamon Fruit Puree manufactured by - Austrofood | | | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar | | | | | |
| | Strength | | If Other | | | | |
| | NDC number | | | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | Yes | | | | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | | | | | |
| Dr | Orug Therapy 1 of 1 | | | | | | |
| | Expiration date | | | | | | |
| | Lot number | | | | | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 13:15:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| | 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 | | | |
| | Date the person stopped taking or using the product | 26-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 | oduct? (such as what cor | ndition was it supposed to t | treat) 1 of 1 | |
| | it is a snack for children - in her lu | | | | |
| | Returned to Manufacturer On | | | | |
| Se | ction D - About the Medical De | evice | | | |
| 00 | Name of medical device | 7/100 | | | |
| | 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 | expiration date, if you can | |
| | | | | | |
| | Model Number | | | | |
| | Catalog Number | | | | |
| | Lot Number | | | | |
| Ш | 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 pacemaker | rs, breast implants, etc.) | | |
| Da | ate the implant was put in | | Date the implant was taken o relevant) | ut (If | |
| Se | ction E - About the Person Wh | o Had the Problem | | | |
| | Person's Initials | (b)(6) | | | |
| | Sex | Female | | | |
| | Gender | Cisgender woman/girl | | | |
| | Oction | | | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 13:15:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| | Age (specify unit of time for age) | | |
|----------|------------------------------------|--|--|
| | Date of Birth | (b)(6) | |
| | Weight | 12.15 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) | |
| | none | | |
| Ple | ease list all allergies (such as t | o drugs, foods, pollen or others) | |
| | none | | |
| Lis | st any other important informati | ion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | none | | |
| Lis | st all current prescription medic | cations and medical devices being used. | |
| lig | none | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| <u> </u> | none | end and any mamino, minoralo, supplements, and herbar remedies being used. | |
| Se | ection F - About the Person Fill | ing Out This Form 1 of 1 | |
| | Primary? | Yes | |
| | Reporter is Patient? | | |
| | Title | | |
| | Last name | (b)(6) | |
| | Middle Name | | |
| | First name | (b)(6) | |
| | Number/Street | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 13:15:29 Page 4 of 5

CTU No.: FDA-CDER-CTU-2023-86279 | Department: CFSAN | RCT No.: RCT-1182388 | CTU Triage Date: 27-Nov-2023 | Total Pages: 5

| City | (b)(6) |
|---|---------------|
| State/Province | |
| Country | UNITED STATES |
| ZIP or Postal code | (b)(6) |
| Telephone number | (h)(6) |
| Email address | (b)(6) |
| 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)? | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | No |

Generated by: SYSTEM Generated on: 25-Nov-2023 13:15:29 Page 5 of 5

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

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

| | yed in the report are in EST(G | wir-os.oo) uine zone | | | | | |
|----------------------------------|--------------------------------|--|--|----------------------------|--|--|--|
| Basic Deta | | CDED CTU | Origination Assessment | FAEDO | | | |
| Company U | | CDER-CTU | Originating Account | FAERS | | | |
| Source Medium | | MWO (Drug) | Source Form Type | E2B XML 3500B | | | |
| Priority | | Routine | | | | | |
| | uto Calculation Rule | No | | | | | |
| FDA Receiv | | 25-Nov-2023 | CTU Received Date | 25-Nov-2023 | | | |
| CTU Triage | | | CTU Data Entry Date | | | | |
| Report Typ | e | Spontaneous | Report Classification | Drug | | | |
| Assign To | | User | | | | | |
| User/Group | 1 | | | | | | |
| Forward to | Department | | | | | | |
| Case Priori | ty | Direct | | | | | |
| | | | | | | | |
| Contact | | | | | | | |
| Case Reporter | First Name | Last Name | Email Address | Phone | | | |
| | (b)(6) | (b)(6) | (b)(6) | (b)(6) | | | |
| Section A | - About the Problem | | | | | | |
| | nd of problem was it? | | | | | | |
| | all that apply) | Were hurt or had a bad side effect (including new or worsening symptoms) | | | | | |
| | | | ich could have or led to a problem | | | | |
| | | Noticed a problem with the qu | | | | | |
| Date the | problem occurred | 16-Nov-2023 | from one product maker to another maker | | | | |
| Serious | · | Yes | | | | | |
| Did any 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) | | | | | |
| | hat happened and how | | s many details as possible FDA | may reach out to you for | | | |
| | een feeding my son (b)(6 | | puree apple sauce for 2 months. I fo | ound out the baby food was | | | |
| recalled | 11/24/2023 through my A | Aunt and grandmother contac | ting saying they seen the recall on t | he news. I've been to the | | | |
| | | | k vomiting, belly aches, irritable 10/1 November 16,2023 was his well che | | | | |
| (b)(6) | s | he later called me about his l | Blood work stating he had high level | s of lead and prescription | | | |
| was wai | ting at the pharmacy in (b |)(6) | . I can be reach at (| (b)(6) | | | |
| | | | | | | | |
| Relevant T | est/Laboratory Data | | | 1 of 1 | | | |
| Test Na | me | CBC(PLATELETS) LEAD | Test Date | 16-Nov-2023 | | | |
| | | BLOOD COMPLETE AS D | | | | | |
| Test Re | sult | | Test Unit | | | | |

Generated by: SYSTEM Generated on: 25-Nov-2023 14:45:22 Page 1 of 5

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

es: 5

| | Low Test Range | | High Test Range | Lead poisioning | |
|----|--|--|-----------------|-----------------|--|
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | I will be getting his MyChart results Monday 11/27/2023 December 13,2023 for lead level check and well check | | | | |
| 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 fruit puree pouch | | | |
| | Name of the company that makes (or compounds) the product | Weis, WanaBana, Schnucks | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar | | | |
| | Strength | | If Other | | |
| | NDC number | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | No | | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | 30-Nov-2023 | | | |
| | Lot number | | | | |
| | Dosage Form | | | | |
| | Quantity | Other | | pouch | |
| | Frequency | 3 times a day | If Other | | |
| | How was it taken or used | Oral | If Other | | |
| | Date the person first started | 14-Sep-2023 | | | |

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