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

| | More Information Available? | | | | |
|----|---|--|----------------------------|--------|--|
| Ad | ditional Comments | | | | |
| | | | | | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? | No | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | No | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wana Bana apple sauce po | ouches | | |
| | Name of the company that makes (or compounds) the product Product Type(check all that apply) | Wana bana Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar | or an Outsourcing Facility | | |
| | Strength | | If Other | | |
| | NDC number | | ı | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | | | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | | | | |
| | Lot number | | | _ | |
| | Dosage Form | | | | |
| | Quantity | | If Other | | |
| | Frequency | | If Other | | |
| | How was it taken or used | | If Other | | |
| | Date the person first started taking or using the product | 01-Sep-2022 | | | |
| | Date the person stopped taking | 06-Nov-2023 | | | |

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or using the product

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| | Date the person reduced dose of the product | | |
|----|---|---|--|
| | Give best estimate of duration | | |
| | Is therapy still on-going? | | |
| W | ny was the person using the pr | oduct? (such as what condition was it supposed to treat) 1 of 1 | |
| | To eat | | |
| | Returned to Manufacturer On | | |
| Se | ection D - About the Medical De | evice | |
| | Name of medical device | | |
| | Name of the company that makes the medical device | | |
| Ot | | 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.) | |
| 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) | |
| | Sex | Male | |
| | Gender | Not selected | |
| | Please Specify Other Gender | | |
| | Age (specify unit of time for age) | 2 Year(s) | |
| | Date of Birth | | |
| | Weight | 10.8 kg | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | |
| | Race (Check all that apply) | American Indian or Alaska Native | |
| | | Native Hawaiian or Other Pacific Islander | |
| | | Asian | |

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

| | | White Black or African American | |
|-------|---|---|--------------------|
| ll is | List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) Lead poisoning Please list all allergies (such as to drugs, foods, pollen or others) List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices being used. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. Section F - About the Person Filling Out This Form 1 of 1 Primary? Yes Reporter is Patient? Title Last name Number/Street City StateProvince Country UNITED STATES | | |
| | | | , 0.1 0.1.0.10) |
| Ple | ease list all allergies (such a | s to drugs, foods, pollen or others) | |
| | | | |
| Lis | st any other important inform | ation about the person (such as smoking, pregnancy, alcohol | use, etc.) |
| | | | |
| Lis | st all current prescription me | dications and medical devices being used. | |
| | | | |
| Lis | st all over-the-counter medic | ations and any vitamins, minerals, supplements, and herbal re | medies being used. |
| | | | |
| | | | |
| Se | | | 1 of 1 |
| | | Yes | |
| | | | |
| | | (h)(6) | |
| | | | |
| | | (h)(6) | |
| | | (D)(O) | |
| | City | | |
| | State/Province | | |
| | Country | UNITED STATES | |
| | ZIP or Postal code | (h)(G) | |
| | Telephone number | (b)(6) | |
| | Email address | | |

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

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CTU No.: FDA-CDER-CTU-2023-82274 | Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pag

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

Contact

| 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 | 07-Nov-2023 | CTU Received Date | 07-Nov-2023 | |
| CTU Triage Date | | CTU Data Entry Date | | |
| Report Type | Spontaneous | Report Classification | Drug | |
| Assign To | User | | , | |
| User/Group | | | | |
| Forward to Department | CDER (CDER-C | CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B) | | |
| Case Priority | Direct | | | |

| Ca Re | se porter | First Name | | Last Name | | Email Address | | Phone | |
|----------|--------------|---|--------|---|---------------------------------|-------------------------|----|--------|--|
| V | | (b)(6) | | (b)(6) | (| b)(6) | | (b)(6) | |
| Se | ction A - | About the Prob | lem | | _ | | | | |
| | | nd of problem was all that apply) | | Were hurt or had a bad si Used a product incorrectly Noticed a problem with th Had problems after switch | which could have quality of the | ave or led to a problem | ı | | |
| | Date the | problem occurred | 03- | Nov-2023 | | | | | |
| | Serious | | Yes | 3 | | | | | |
| | - | of the following ha all that apply) | | Hospitalization - admitted Required help to prevent Disability or health proble Birth defect Life-threatening Death Other serious/important m | permanent harn | n | w) | | |
| | | rious/important mo Please Describe E | edical | | | | | | |

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)

Our daughter was born on (b)(6) . We purchased Wana Bana cinnamon apple baby purée from Dollar Tree in September 2023. Our infant ate approximately 12 packets. We have extra packets she has not eaten at home. We saw the recall for Wana Bana apple cinnamon baby October 30, 2023 for high levels of lead. We were seen by our pediatrician on October 31, 2023. Had blood drawn for lead. Received results from Pediatrician on 11/3/2023 with serum lead results at 20.4 mcg/dL. She has been referred to Hematology. She was also placed on an iron supplement in the meantime.

| R | Relevant Test/Laboratory Data 1 | | | |
|---|---------------------------------|-------------|-----------|-------------|
| | Test Name | SERUM LEAD | Test Date | 31-Oct-2023 |
| | Test Result | 20.4 mcg/dL | Test Unit | UNKNOWN |

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| es: | 7 | |
|-----|---|--|
| | | |

| | Low Test Range | | High Test Range | | |
|----|---|---|------------------------------------|--------|--|
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | | | | | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? | Yes | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | Yes | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wana Bana Apple Cinnamo | na Bana Apple Cinnamon Fruit Purée | | |
| | 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? | | | | |
| | Did the problem return if the person started taking or using the product again? | | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | 26-Jun-2024 | | | |
| | Lot number | 04023:26 | | | |
| | Dosage Form | | 1 | | |
| | Quantity | | If Other | | |
| | Frequency | | If Other | | |
| | How was it taken or used | | If Other | | |
| | Date the person first started taking or using the product | | | | |

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CTU No.: FDA-CDER-CTU-2023-82274 | Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pages: 7

| | Date the person stopped taking or using the product | | | |
|-----|---|-------------------------------|--|--------------------------|
| | Date the person reduced dose of the product | | | |
| | Give best estimate of duration | 1 Month | | |
| | Is therapy still on-going? | | | |
| Wł | ny was the person using the pr | oduct? (such as what co | ndition was it supposed to treat | 1 of 1 |
| | Baby food | | | |
| | | | | |
| | Returned to Manufacturer On | | | |
| Se | ection D - About the Medical De | evice | | |
| | Name of medical device | | | |
| | Name of the company that makes the medical device | | | |
| Ot | | e model, catalog, lot, seri | al, or UDI number, and the exp | iration date, if you can |
| loc | cate them) | | <u> </u> | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | Model Number | | | |
| | Catalog Number | | | |
| | Lot Number | | | |
| | Serial Number | | | |
| | UDDI Number | | | |
| | Expiration date | | | |
| | Was someone operating the medical device when the problem occurred? | | | |
| Fo | r implanted medical devices O | NLY (such as pacemake | ers, breast implants, etc.) | |
| | ate the implant was put in | | Date the implant was taken out (If relevant) | |
| Se | ction 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 | 7.65 kg | | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | | |
| | Race (Check all that apply) | American Indian or Alaska Na | tive | |
| | | Native Hawaiian or Other Paci | | |

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CTU No.: FDA-CDER-CTU-2023-82274 | Department: CFSAN | RCT No.: RCT-1178180 | CTU Triage Date: 08-Nov-2023 | Total Pag

es: 7

| | Asian White Black or African American | |
|-----|--|---|
| Lis | st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | None prior to discovery of high lead levels | |
| PΙ | ease list all allergies (such as to drugs, foods, pollen or others) | |
| | None | |
| Lis | st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | |
| Lis | st all current prescription medications and medical devices being used. | |
| | | |
| Lis | st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | Poly Vi Sol multivitamin | |
| Se | ection F - About the Person Filling Out This Form 1 of 1 | |
| | Primary? Yes | |
| | Reporter is Patient? | |
| | Title | |
| | Last name (b)(6) | |
| | Middle Name | |
| | First name (6)(6) | |
| | Number/Street (b)(6) | |
| | City | _ |
| | State/Province LINITED STATES | - |
| | Country UNITED STATES ZIP or Postal code | |
| | ZIP or Postal code Telephone number Email address | - |
| | Email address | |

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

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

| asic Details | | | | | |
|---------------------------------------|--|-----------------------|--------------|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500 | | |
| riority | Routine | | | | |
| Override Auto Calculation Rule | No | | | | |
| DA Received Date | 08-Nov-2023 | CTU Received Date | 08-Nov-2023 | | |
| CTU Triage Date | | CTU Data Entry Date | | | |
| Report Type | Spontaneous | Report Classification | Drug | | |
| ssign To | User | | J | | |
| Jser/Group | | | | | |
| Forward to Department | | | | | |
| Case Priority | Direct | | | | |
| | <u>I</u> | | | | |
| ontact | | | | | |
| Case First Name | Last Name | Email Address | Phone | | |
| Reporter (b)(6) | (b)(6) | (h)(6) | (b)(6) | | |
| (p)(p) | (D)(O) | (b)(6) | (6)(0) | | |
| . PATIENT INFORMATION | | | | | |
| Patient Identifier (In Confidence) | (b)(6) | | | | |
| Age | 28 Month(s) | | _ | | |
| Date of Birth | | | | | |
| Sex | Male | | | | |
| Gender | Cisgender man/boy | | | | |
| Please Specify Other Gender | | | | | |
| Weight | 13.2 kg | | | | |
| Ethnicity (Check single best | Not Hispanic/Latino | | | | |
| answer) | | | | | |
| Race (Check all that apply) | Asian | | | | |
| | American Indian or Alas | ska Native | | | |
| | Black or African American | | | | |
| | White | | | | |
| | Native Hawaiian or Othe | er Pacific Islander | | | |
| . ADVERSE EVENT, PRODUC | TPROBLEM | | | | |
| Type of Report (check all that apply) | Adverse Event | | | | |
| арріу) | Product Use/Medication | Error | | | |
| | Product Problem (e.g., defects/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 | prolonged) | | | |
| | Other Serious or Import | | | | |
| | Disability or Permanent | | | | |

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CTU No.: FDA-CDER-CTU-2023-82538 | Department: CFSAN | RCT No.: RCT-1178375 | CTU Triage Date: 09-Nov-2023 | Total Pag

| | Congenital Anomaly/Birth Def | ooto | |
|--|-------------------------------|--------------------------------------|---------------------------------------|
| | | ects ent Permanent Impairment/Damage | |
| Date of Death | Nequired intervention to Frev | ent Fermanent impairment Damage | |
| Date of Event | 01-Nov-2023 | _ | |
| Date of this Report | 08-Nov-2023 | | |
| escribe Event, Problem or Prod | | | |
| | | ed 3-4 pouches of Wana Bana | a apple fruit puree. He tested for ar |
| elevant Test/Laboratory Data | | | 1 of 1 |
| Test Name | VENOUS BLOOD LEAD | Test Date | 01-Nov-2023 |
| Test Result | 8.1 | Test Unit | MICROGRAMS PER DEC |
| Low Test Range | <3.4 | High Test Range | ILITIAL |
| More Information Available? | | | |
| | | | |
| ther Relevant History, Including | g Preexisting Medical Co | nditions | |
| | g Preexisting Medical Co | nditions | |
| | | nditions | |
| PRODUCT AVAILABILITY Product Available for Evaluation? | | nditions | |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) | | nditions | |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are including a picture) | No | nditions | 1 of 1 |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are including a picture) | No | nditions | 1 of 1 |
| (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are including a picture) PRODUCT(S) | No No | nditions | 1 of 1 |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are including a picture) PRODUCT(S) Suspect Primary? | No No Yes Yes | nditions | 1 of 1 |
| PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Returned to Manufacturer on Do you have a picture of the product? (check yes if you are including a picture) PRODUCT(S) Suspect | No No Yes | nditions | 1 of 1 |

Strength If Other

Manufacturer/Compounder

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Wana Bana

Product Name

CTU No.: FDA-CDER-CTU-2023-82538 | Department: CFSAN | RCT No.: RCT-1178375 | CTU Triage Date: 09-Nov-2023 | Total Pag

| | 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? | | | J | |
| | Lot Number | | | | |
| | Evaluation Data | | | | |
| | Expiration Date | | | | |
| Di | Expiration Date agnosis for Use (indication) | | | 1 of 1 | |
| Di | | | | 1 of 1 | |
| Di | | | | 1 of 1 | |
| Di | | | | 1 of 1 | |
| Di | | | | 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 | | | 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 # 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 | | 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 | |

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| | 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 PRODU | | |
| | | | |
| G. | REPORTER | 1 of 1 | |
| | Primary? | Yes | |
| | Reporter is Patient? | | |
| | Title | | |
| | Last Name | (b)(6) | |
| | Middle Name | | |
| | First Name | /1- \ / () | |
| | Address | (n)(n) | |
| | City | (b)(6) | |
| | State/Province/Region | | |
| | Country | UNITED STATES If Other | |
| | ZIP/Postal Code | (h)(C) | |
| | Phone | | |
| | Email | | |
| | Fax | | |
| | Reporter Organization | | |
| | Department | | |
| | Reporter Speciality | | |
| | Health Professional? | Yes | |
| | Occupation | Physician If Other | |
| | Also Reported to | ☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer | |
| | If you do NOT want your identity | No | |

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CTU No.: FDA-CDER-CTU-2023-82566 | Department: CFSAN | RCT No.: RCT-1178434 | CTU Triage Date: 09-Nov-2023 | Total Pag

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

| Basic Details | | | |
|--------------------------------|-------------|-----------------------|---------------|
| Company Unit | CDER-CTU | Originating Account | FAERS |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B |
| Priority | Routine | | J |
| Override Auto Calculation Rule | No | | |
| FDA Received Date | 08-Nov-2023 | CTU Received Date | 08-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) | |
| Section A | - About the Problem | | | | | | |
| \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ | | Used a product incorrectly Noticed a problem with th | 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 | e problem occurred | 07-Nov-2023 | | | | | |
| Serious | | Yes | | | | | |
| Did any of the following happen? (Check all that apply) | | Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) | | | | | |
| Other serious/important medical incident(Please Describe Below) | | | | | | | |
| 4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to any additional documents if necessary) | | | | y reach out to | you for | | |
| | ler had a wanabana applet & his tests came back hi | • | day it hit na | ational news that they v | vere recall | ed. I took him in | to get a |

| Relevant Test/Laboratory Data 1 of 1 | | | | |
|--------------------------------------|-----------|-----------|----------------------|--|
| Test Name | LEAD TEST | Test Date | 07-Nov-2023 | |
| Test Result | 6.1 | Test Unit | MILLIGRAMS PER DECIL | |

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es: 6

| | Low Test Range | | High Test Range | | |
|----|---|---|-------------------------|--------|----------|
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | | | | | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? | No | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | Yes | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wana Bana Mango & Banan | а | | |
| | Name of the company that makes (or compounds) the product | Wana Bana | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy or Generic Biosimilar | an Outsourcing Facility | | |
| | Strength | | If Other | | |
| | NDC number | _ | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | | | | |
| | Did the problem return if the person started taking or using the product again? | | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | _ | | | <u> </u> |
| | Lot number | | | | |
| | Dosage Form | 1 | 15 011 | | |
| | Quantity | | If Other | | |
| | Frequency | | If Other | | - |
| | How was it taken or used | | If Other | | |
| | Date the person first started | | | | |

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CTU No.: FDA-CDER-CTU-2023-82566 | Department: CFSAN | RCT No.: RCT-1178434 | CTU Triage Date: 09-Nov-2023 | Total Pag

| | Date the person stopped taking or using the product | | | | | | |
|-----|---|-------------|---|--------------------------------------|----------|------------------------|--|
| | Date the person reduced dose of the product | | | | | | |
| | Give best estimate of duration | | | | | | |
| | Is therapy still on-going? | | | | | | |
| W | hy was the person using the pr | oduct? (su | ich as what co | ondition was it supposed to | treat) | 1 of 1 | |
| | | | | | | | |
| | Returned to Manufacturer On | | | | | | |
| Se | ection D - About the Medical De | evice | | | | | |
| | Name of medical device | | | | | | |
| | Name of the company that makes the medical device | | | | | | |
| | her identifying information (The | e model, ca | atalog, lot, sei | rial, or UDI number, and the | e expira | ation date, if you can | |
| 100 | cate them) | | | | | | |
| | | | | | | | |
| | Model Number | | | | | | |
| | Catalog Number | | | | | | |
| | Lot Number | | | | | | |
| | Serial Number | | | | | | |
| | UDDI Number | | | | | | |
| | Expiration date | | | | | | |
| | Was someone operating the medical device when the problem occurred? | | | | | | |
| Fo | or implanted medical devices O | NLY (such | n as pacemak | ers, breast implants, etc.) | | | |
| D | ate the implant was put in | | | Date the implant was taken relevant) | out (If | | |
| Se | ection E - About the Person Wh | | Problem | | | | |
| | Person's Initials | (b)(6) | | | | | |
| | Sex | Male | | | | | |
| | Gender | Cisgender | man/boy | | | | |
| | Please Specify Other Gender | | | | | | |
| | Age (specify unit of time for age) | 1 Year(s) | | | | | |
| | Date of Birth | | | | | | |
| | Weight | 9.45 kg | | | | | |
| | Ethnicity (Choose only one) | Not Hispar | nic/Latino | | | | |
| | Race (Check all that apply) | | n Indian or Alaska N awaiian or Other Pa | | | | |

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es: 6

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

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es: 6

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

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

| Basic Details | | | | | | |
|---|--------------|--------------------------------|---|---------------|--|--|
| Company Unit | | CDER-CTU | Originating Account | FAERS | | |
| Source Medium | | MWO (Drug) | Source Form Type | E2B XML 3500B | | |
| Priority | | Routine | | | | |
| Override Auto Calculation Rule | | No | | | | |
| FDA Received Date | | 10-Nov-2023 | CTU Received Date | 10-Nov-2023 | | |
| CTU Triage Date | | | CTU Data Entry Date | | | |
| Report Type | | Spontaneous | Report Classification | Drug | | |
| Assign To | | User | | | | |
| User/Group | | | | | | |
| Forward to Departm | ent | CDER (CDER-OSE-R | SS-CTU@fda.hhs.gov) (E2B) | | | |
| Case Priority | | Direct | | | | |
| Case First N Reporter (b)(6 | | (b)(6) | Email Address (b)(6) | Phone (b)(6) | | |
| Section A - About | the Problem | | | | | |
| What kind of pro (Check all that a | blem was it? | Used a product incorrectly whi | ffect (including new or worsening sympt ich could have or led to a problem ality of the product from one product maker to another mak | | | |
| Date the problem occurred 03-Nov-2023 | | 03-Nov-2023 | | | | |
| Serious | Serious Ye | | Yes | | | |
| Did any of the following happen? (Check all that apply) | | | | | | |

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

Other serious/important medical incident(Please Describe Below)

Life-threatening

Death

Other serious/important medical incident(Please Describe Below)

My daughter consumed Wana Bana pouches from February 2023 until the date of the recall. Her bloodwork indicates a lead level of 7.4. Her bloodwork levels were normal at her one year check up. The only thing that has changed about her diet or environment is giving her the pouches.

| F | Relevant Test/Laboratory Data 1 of 1 | | | | | |
|---|--------------------------------------|-------------|-----------|--------------------|--|--|
| | Test Name | LEAD VENOUS | Test Date | 03-Nov-2023 | | |
| | Test Result | 7.4 | Test Unit | MICROGRAMS PER DEC | | |

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| 0 | 0 | ٠ | |
|---|---|---|---|
| C | 0 | ٠ | · |

| | Low Test Range | | High Test Range | | |
|-----|---|---|----------------------------|--------|--|
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | | | | | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? | Yes | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | No | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wana Bana Apple Cinnamo | on Fruit Puree | | |
| | Name of the company that makes (or compounds) the product | Austrofood SAS | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar | or an Outsourcing Facility | | |
| | Strength | | If Other | | |
| | NDC number | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | | | | |
| | Did the problem return if the person started taking or using the product again? | | | | |
| Dru | ug Therapy | | | 1 of 1 | |
| | Expiration date | | | | |
| | Lot number | 01023:23 | | | |
| | 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 | 26-Feb-2023 | | | |

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| | Date the person stopped taking or using the product | | 27-Oct-2023 | | | | | |
|-----|---|-----|---------------------|---------|--------|--|------------------------|---|
| | Date the person reduced dose of the product | | | | | | | |
| | Give best estimate of duration | T | | | | | | |
| | Is therapy still on-going? | | | | | | | |
| W | hy was the person using the pr | ro | duct? (such as v | /hat | cor | ndition was it supposed to treat) | 1 of 1 | |
| | Nutrition, not for medical condition | n t | reatment | | | | | |
| | Returned to Manufacturer On | | | | | | | |
| Se | ection D - About the Medical De | e١ | rice | | | | | |
| | Name of medical device | | | | | | | |
| | Name of the company that makes the medical device | | | | | | | |
| | | е | model, catalog, l | ot, s | seria | al, or UDI number, and the expira | ition date, if you can | |
| 100 | cate them) | | | | | | | |
| | | | | | | | | |
| | Model Number | | | | | | | |
| | Catalog Number | | | | | | | |
| | Lot Number | | | | | | | |
| | Serial Number | | | | | | | |
| | UDDI Number | | | | | | | |
| | Expiration date | | | | | | | |
| | Was someone operating the medical device when the problem occurred? | 1 | | | | | | |
| Fo | r implanted medical devices O | 70 | LY (such as pac | ema | aker | s, breast implants, etc.) | | |
| D | ate the implant was put in | | | | | Date the implant was taken out (If relevant) | | |
| Se | ection E - About the Person Wh | าด | Had the Proble | n | | | | |
| | 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 | | | | | | | |
| | Ethnicity (Choose only one) | | Not Hispanic/Latino |) | | | | |
| | Race (Check all that apply) | | American Indian or | Alaska | a Nati | ve | | |
| | | | Native Hawaiian or | Other [| Pacif | ic Islander | | ĺ |

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| | Asian White Black or African American | |
|------|--|----------|
| l is | st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | removini modical containere (eden de diabetee, mgm biece precedire, cameer, meart diecede, er enreie) | |
| | | |
| PΙ | ease list all allergies (such as to drugs, foods, pollen or others) | |
| | | |
| Lis | st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | |
| Lis | st all current prescription medications and medical devices being used. | |
| | | |
| Lis | st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | | |
| Se | ection F - About the Person Filling Out This Form 1 of 1 | |
| | Primary? Yes | |
| | Reporter is Patient? | |
| | Title | |
| | Last name (b)(6) | |
| | Middle Name | |
| | First name | _ |
| | Number/Street | <u> </u> |
| | Number/Street City Otata/Pressions | - |
| | State/Province | |
| | | |
| | ZIP or Postal code Telephone number Email address | |
| | Email address | |

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| Fax | | |
|---|-------------|--|
| Reporter Organization | | |
| Department | | |
| Reporter Speciality | | |
| Today's date | 10-Nov-2023 | |
| Did you report this problem to the company that makes the product (the manufacturer/compounder)? | No | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | No | |

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

| Basic Deta | nils | | | |
|------------------|--|---|-----------------------|--------------|
| Company L | Jnit | CDER-CTU | Originating Account | FAERS |
| Source Med | dium | MWO (Drug) | Source Form Type | E2B XML 3500 |
| Priority | | Routine | | <u> </u> |
| Override Au | uto Calculation Rule | No | | |
| FDA Receiv | ved Date | 11-Nov-2023 | CTU Received Date | 11-Nov-2023 |
| CTU Triage | e Date | | CTU Data Entry Date | |
| Report Typ | 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 |
| Z | (b)(6) | (b)(6) | (b)(6) | (b)(6) |
| A PATIEN | IT INFORMATION | | | |
| | Identifier (In Confidence) | Unspecified | | |
| Age | | Споросинов | | |
| Date of | Birth | (b)(6) | | |
| Sex | | Male | | |
| Gender | | Cisgender man/boy | | |
| | Specify Other Gender | Clagerider manyboy | | |
| Weight | opeany outer conder | 11.7 kg | | |
| _ | y (Check single best | Not Hispanic/Latino | | |
| answer) | = | | | |
| Race (C | Check all that apply) | Asian American Indian or Alask Black or African America White Native Hawaiian or Othe | n | |
| B. ADVER | SE EVENT, PRODUC | T PROBLEM | | |
| | Report (check all that | Adverse Event Product Use/Medication Product Problem (e.g., d | | |
| Serious | | Yes | | |
| | e Attributed to Adverse Check all that apply) | Death Life Threatening Hospitalization (initial or Other Serious or Importa Disability or Permanent I | nt Medical Events | |

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| ۵ | c | ٠ | 1 | |
|---|---|---|---|--|

| | | Congenital Anomaly/Birth Defects | | | | |
|----|--|----------------------------------|--------------------------------|--------------------|--|--|
| | | Required Intervention to Preve | nt Permanent Impairment/Damage | | | |
| | Date of Death | | | | | |
| | Date of Event | 01-Nov-2023 | | | | |
| | Date of this Report | 11-Nov-2023 | | | | |
| De | Describe Event, Problem or Product Use Error | | | | | |
| | Describe Event, Problem, or Product Use Error: Ingestion of WanaBana cinnamon applesauce. Was given a box for Halloween and had several prior to family hearing about recall. Had appointment in clinic on 11-9-23. Lab draw for lead level. Was elevated at 6.7 (reference < 3.4) | | | | | |
| Re | levant Test/Laboratory Data | | | 1 of 1 | | |
| | Test Name | LEAD, BLOOD | Test Date | 09-Nov-2023 | | |
| | Test Result | 6.7 | Test Unit | MICROGRAMS PER DEC | | |
| | Low Test Range | | High Test Range | ILITRE 3.4 | | |
| | More Information Available? | | <u> </u> | | | |
| Ad | ditional Comments | | | | | |
| Ot | Other Relevant History, Including Preexisting Medical Conditions | | | | | |
| | | | | | | |
| C. | PRODUCT AVAILABILITY | <u> </u> | | | | |
| | 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 I | label) | | | |
| | Product Name | WanaBana Cinnamon Apple | esauce | | | |
| | Strength | | If Other | | | |
| | Manufacturer/Compounder | | | | | |

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| | NDC# or Unique ID | | | | |
|-----|---|--------------------------------------|----------|--------|--|
| | Product Type(check all that | Отс | | | |
| | apply) | Compounded | | | |
| | | Generic | | | |
| | | Biosimilar | | | |
| | Event Abated After Use Stopped or Dose Reduced? | | | | |
| | Event Reappeared after Reintroduction ? | | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Dose or Amount | | If Other | 1 27 7 | |
| | Frequency | | If Other | | |
| | Route | Oral | If Other | | |
| | Dosage Form | | | | |
| | Start | | | | |
| | Stop | | | | |
| | Dose Reduced | | | - | |
| | Therapy Duration | | If Other | | |
| | Is therapy still on-going? | | | , | |
| | Lot Number | | | | |
| ı | Expiration Data | | | | |
| | 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 | | | 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 # 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 | | 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)# | | | 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 | |

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CTU No.: FDA-CDER-CTU-2023-83256 | Department: CFSAN | RCT No.: RCT-1179210 | CTU Triage Date: 13-Nov-2023 | Total Pag

| | 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 PRODI | UCT DESCRIPTION | |
| | | | |
| | | | |
| | | | |
| | | | |
| G. | REPORTER | 1 of 1 | |
| | Primary? | Yes | |
| | Reporter is Patient? | | |
| | Title | | |
| | Last Name | b)(6) | |
| | Middle Name | (b)(6) | |
| | First Name | (h)(6) | |
| | Address | (D)(O) | |
| | City | | |
| | State/Province/Region | | |
| | Country | UNITED STATES If Other | |
| | ZIP/Postal Code | (h)(c) | |
| | Phone | | |
| | Email | | |
| | Fax | | |
| | Reporter Organization | | |
| | Department | | |
| | Reporter Speciality | | |
| | Health Professional? | Yes | |
| | Occupation | Nurse Practitioner If Other | |
| | Also Reported to | ☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer | |
| | If you do NOT want your identity disclosed to the manufacturer | No | |

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

| Basic Details | | | | | |
|--------------------------------|---|-----------------------|---------------|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B | | |
| Priority | Routine | | | | |
| Override Auto Calculation Rule | No | | | | |
| FDA Received Date | 13-Nov-2023 | CTU Received Date | 13-Nov-2023 | | |
| CTU Triage Date | | CTU Data Entry Date | | | |
| Report Type | Spontaneous | Report Classification | Drug | | |
| Assign To | User | | | | |
| User/Group | | | | | |
| Forward to Department | CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B) | | | | |
| Case Priority | Direct | | | | |
| | | | | | |
| | | | | | |

| Conta | act | | | | |
|--------------|---|--|---|--------|--|
| Case Repo | | Last Name | Email Address | Phone | |
| | (b)(6) | (b)(6) | (b)(6) | (b)(6) | |
| Section | on A - About the Problem | | | | |
| 1 1 | hat kind of problem was it? Check all that apply) | Used a product incorrectly Noticed a problem with the | le effect (including new or worsening sympt which could have or led to a problem e quality of the product ing from one product maker to another mak | | |
| Da | ate the problem occurred | 16-Jun-2023 | | | |
| Se | erious | No | | | |
| 1 1 | d any of the following happen? Check all that apply) | Hospitalization - admitted of Required help to prevent p Disability or health problen Birth defect Life-threatening Death Other serious/important me | permanent harm | | |
| any a | 1. 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) 2 year old had elevated blood lead levels resulted in eating Wana Bana fruit pouches, which recently came out in the news as having been tested high for lead. | | | | |

| R | Relevant Test/Laboratory Data 1 of 2 | | | | | |
|---|--------------------------------------|-------------|-----------------|------------------------------|--|--|
| | Test Name | LEAD, BLOOD | Test Date | 16-Jun-2023 | | |
| | Test Result | 8.6 | Test Unit | MICROGRAMS PER DEC ILITRE | | |
| | Low Test Range | | High Test Range | | | |

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| | More Information Available? | | | | |
|----|--|---|-----------------------------------|--------------------------|---|
| Re | levant Test/Laboratory Data | | | 2 of 2 | |
| | Test Name | LEAD, BLOOD | Test Date | 28-Sep-2023 | |
| | Test Result | 1.9 | Test Unit | MICROGRAMS PER LITR E | |
| | Low Test Range | | High Test Range | | |
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | Lead level went down after having | g my child refrain from eating | these fruit pouches (about a mont | th and a half later). | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? | No | | | |
| | Do you have a picture of the product? (check yes if you are including a picture) | No | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | _ |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | Wana Bana fruit pouches | | | |
| | Name of the company that makes (or compounds) the product | 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 | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | | | | |
| 1 | Let number | | | | |

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CTU No.: FDA-CDER-CTU-2023-83362 | Department: CFSAN | RCT No.: RCT-1179311 | CTU Triage Date: 13-Nov-2023 | Total Pag

| | Dosage Form | | | | |
|-----|--|---|--------------------------------------|-------------------------------|----------|
| | Quantity | | If Other | | |
| | Frequency | | If Other | | |
| | How was it taken or used | | If Other | | |
| | Date the person first started taking or using the product | 01-Aug-2022 | | | |
| | Date the person stopped taking or using the product | 07-Aug-2023 | | | |
| | Date the person reduced dose of the product | | | | |
| | Give best estimate of duration | | | | |
| | Is therapy still on-going? | | | | |
| Wł | ny was the person using the pr | roduct? (such as what co | endition was it supposed to | treat) 1 of 1 | |
| | | | | | |
| | Returned to Manufacturer On | | | | |
| S0 | ction D - About the Medical De | ovico | | | |
| 00 | Name of medical device | evice | | | <u> </u> |
| | Name of the company that | | _ | | |
| | and the state of t | | | | |
| Otl | her identifying information (The ate them) | e model, catalog, lot, ser | ial, or UDI number, and th | e expiration date, if you can | |
| | | | | | |
| | Model Number | | | | |
| | Catalog Number | | _ | | |
| | Lot Number | | _ | | |
| | Serial Number | | _ | _ | |
| | UDDI Number | | _ | | |
| | Expiration date | | _ | | |
| | Was someone operating the medical device when the problem occurred? | | | | |
| Fo | r implanted medical devices O | NLY (such as pacemake | ers, breast implants, etc.) | | |
| | ate the implant was put in | | Date the implant was taken relevant) | out (If | |
| Se | ction E - About the Person Wh | no Had the Problem | | | |
| | Person's Initials | (b)(6) | | | |
| | Sex | Male | | | |
| | Gender | Cisgender man/boy | _ | | |
| | Please Specify Other Gender | , | | | |
| | | | | | |

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| - 6 | 38 | ١. | O |
|-----|----|----|---|

| | Age (specify unit of time for age) | 2 Year(s) | |
|------|------------------------------------|--|---|
| | Date of Birth | | |
| | Weight | 17.1 kg | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | |
| | Race (Check all that apply) | | |
| | reace (Official and apply) | ☐ American Indian or Alaska Native | |
| | | ☐ Native Hawaiian or Other Pacific Islander | |
| | | L Asian □ Asian | |
| | | White | |
| | | □ Black or African American | |
| Lis | t known medical conditions (S | uch as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | | | |
| | | | |
| | | | |
| | | | |
| Ple | ease list all allergies (such as t | o drugs, foods, pollen or others) | |
| | <u> </u> | | |
| | | | |
| | | | |
| | | | |
| l io | t any other increases informati | an about the never (eyek as empline programmy clockel use etc.) | _ |
| LIS | t any other important informati | on about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | | |
| | | | |
| | | | |
| | | | |
| Lis | t all current prescription medic | ations and medical devices being used. | |
| | | | |
| | | | |
| | | | |
| | | | |
| Lis | t all over-the-counter medicati | ons and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Se | ction F - About the Person Fill | ing Out This Form 1 of 1 | |
| | Primary? | Yes | |
| | Reporter is Patient? | | |
| | Title | | |
| | | (b)(6) | |
| | Middle Name | | |
| | | (b)(6) | |
| | Number/Street | (b)(6) | |
| | Nullibel/Street | | |

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| City | (b)(6) | |
|---|---------------|---|
| State/Province | | |
| Country | UNITED STATES | |
| ZIP or Postal code | /b\/C\ | |
| Telephone number | (b)(6) | |
| Email address | | |
| Fax | | |
| Reporter Organization | | |
| Department | | Г |
| Reporter Speciality | | Γ |
| Today's date | 13-Nov-2023 | |
| Did you report this problem to the company that makes the product (the manufacturer/compounder)? | | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | Yes | |

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CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag

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

| Basic Details | | | | | |
|--|--|--|---------------|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B | | |
| Priority | Routine | | , | | |
| Override Auto Calculation Rule | No | | | | |
| FDA Received Date | 13-Nov-2023 | CTU Received Date | 13-Nov-2023 | | |
| CTU Triage Date | | CTU Data Entry Date | | | |
| Report Type | Spontaneous | Report Classification | Drug | | |
| Assign To | User | | | | |
| User/Group | | | | | |
| Forward to Department | CDER (CDER-O | SE-RSS-CTU@fda.hhs.gov) (E2B) | | | |
| Case Priority | Direct | | | | |
| Case Reporter (b)(6) | (b)(6) | Last Name Email Address Phone (b)(6) (b)(6) | | | |
| Section A - About the Problem | 1 | | | | |
| What kind of problem was it? (Check all that apply) | Used a product incorred Noticed a problem with | side effect (including new or worsening sympto ctly which could have or led to a problem the quality of the product tching from one product maker to another make | | | |
| Date the problem occurred | 24-Mar-2023 | | | | |
| Serious | Yes | Yes | | | |
| Did any of the following happe (Check all that apply) | Required help to prever | Required help to prevent permanent harm Disability or health problem | | | |

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

Other serious/important medical incident(Please Describe Below)

Life-threatening

Other serious/important medical incident(Please Describe Below)

My son was lead poisoned with a BLL of 13. His consumption of the cinnamon apple pouches made by WanaBana coincide with his poisoning. The DOH was contacted to check our house for possible exposure to which they did not find a plausible source. After I stopped giving my son these pouches his levels continued to drop over the next 6 months until reaching undetectable levels.

| Re | Relevant Test/Laboratory Data 1 of 1 | | | | | |
|----|--------------------------------------|------------------|-----------|-------------------------------|--|--|
| | Test Name | VENOUS LEAD TEST | Test Date | 22-Mar-2023 | | |
| | Test Result | 13 | Test Unit | MICROGRAMS PER MIL LILITRE | | |

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CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag

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| | Low Test Range | 0 | High Test Range | Indefinite | |
|----|--|---|----------------------------|------------|--|
| | More Information Available? | | | | |
| Ad | ditional Comments | | | | |
| | | | | | |
| Se | ction B - Product Availability | | | | |
| | Do you still have the product in case we need to evaluate it? Do you have a picture of the product? (check yes if you are | No | | | |
| | including a picture) | | | | |
| Se | ction C - About the Products | | | 1 of 1 | |
| | Suspect | Yes | | | |
| | Primary? | Yes | | | |
| | Туре | Drug/Biologic | | | |
| | This report is about | Food/Medical food | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | apple cinnamon fruit puree | | | |
| | Name of the company that makes (or compounds) the product | WanaBana | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy of Generic Biosimilar | or an Outsourcing Facility | | |
| | Strength | | If Other | | |
| | NDC number | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | Yes | | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | | | |
| Dr | ug Therapy | | | 1 of 1 | |
| | Expiration date | | | | |
| | Lot number | | | | |
| | Dosage Form | | | | |
| | Quantity | | If Other | | |
| | Frequency | | If Other | | |
| | How was it taken or used | | If Other | | |
| | Date the person first started | | | | |

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CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag

| | Date the person stopped taking or using the product | | | | |
|-----|---|------------------------------|--|---------------------------|--|
| | Date the person reduced dose of the product | | | | |
| | Give best estimate of duration | 2 Month | | | |
| | Is therapy still on-going? | | | | |
| WI | hy was the person using the pr | oduct? (such as what co | ndition was it supposed to trea | t) 1 of 1 | |
| | | | | | |
| | Returned to Manufacturer On | | | | |
| Se | ection D - About the Medical De | evice | | | |
| | Name of medical device | | | | |
| | Name of the company that makes the medical device | | | | |
| | her identifying information (The | e model, catalog, lot, seri | al, or UDI number, and the exp | piration date, if you can | |
| loc | cate them) | | | | |
| | | | | | |
| | Model Number | | | | |
| | Catalog Number | | | | |
| | Lot Number | | | | |
| | Serial Number | | | | |
| | UDDI Number | | | | |
| | Expiration date | | | | |
| | Was someone operating the medical device when the problem occurred? | | | | |
| Fo | or implanted medical devices O | NLY (such as pacemake | rs, breast implants, etc.) | | |
| Da | ate the implant was put in | | Date the implant was taken out (If relevant) | F | |
| Se | ection E - About the Person Wh | no Had the Problem | | | |
| | Person's Initials | (b)(6) | | | |
| | Sex | Male | | | |
| | Gender | Cisgender man/boy | | | |
| | Please Specify Other Gender | | | | |
| | Age (specify unit of time for age) | 12 Month(s) | | | |
| | Date of Birth | | | | |
| | Weight | 7.65 kg | | | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | | | |
| | Race (Check all that apply) | American Indian or Alaska Na | | | |

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| | | Asian White Black or African American | |
|-----|----------------------------------|--|-------|
| Lis | st known medical conditions (S | Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
| | | | |
| PΙ | ease list all allergies (such as | to drugs, foods, pollen or others) | |
| | | | |
| Lis | st any other important informat | tion about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | | |
| Lis | t all current prescription medic | cations and medical devices being used. | |
| | | | |
| Lis | st all over-the-counter medicat | tions and any vitamins, minerals, supplements, and herbal remedies being ι | ısed. |
| | | | |
| Se | ection F - About the Person Fill | ling Out This Form 1 o | 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 | The state of the s | |
| | Country | UNITED STATES | |
| | ZIP or Postal code | (h)(6) | |
| | Telephone number | (b)(6) | |
| | Email address | | |

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CTU No.: FDA-CDER-CTU-2023-83387 | Department: CFSAN | RCT No.: RCT-1179339 | CTU Triage Date: 13-Nov-2023 | Total Pag

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| Fax | | |
|---|-------------|--|
| Reporter Organization | | |
| Department | | |
| Reporter Speciality | | |
| Today's date | 13-Nov-2023 | |
| Did you report this problem to the company that makes the product (the manufacturer/compounder)? | No | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | No | |

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

| Basic Details | | | |
|---|---|---|--|
| Company Unit | CDER-CTU | Originating Account | FAERS |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B |
| Priority | Routine | 1 | |
| Override Auto Calculation Rule | No | | |
| FDA Received Date | 13-Nov-2023 | CTU Received Date | 13-Nov-2023 |
| CTU Triage Date | | CTU Data Entry Date | |
| Report Type | Spontaneous | Report Classification | Drug |
| Assign To | User | | |
| User/Group | | | |
| Forward to Department | CDER (CDER-OSE-R | SS-CTU@fda.hhs.gov) (E2B) | |
| Case Priority | Direct | | |
| | 1 | | |
| Contact | | | |
| Case First Name | Last Name | Email Address | Phone |
| Reporter (b)(6) | (b)(6) | (b)(6) | (b)(6) |
| \(\rho\)(\rho\) | (b)(6) | (b)(o) | (5)(0) |
| Section A - About the Problem | | | |
| What kind of problem was it? (Check all that apply) | Used a product incorrectly whi | ffect (including new or worsening symptoms) ich could have or led to a problem ality of the product from one product maker to another maker | |
| Date the problem occurred | 06-Oct-2023 | | |
| Serious | No | | |
| recall we were going through all t | Required help to prevent perm Disability or health problem Birth defect Life-threatening Death Other serious/important medic w it happened (Include as essary) of or her 12 month well visit and the avenues of what may have | nanent harm rail incident(Please Describe Below) | elevated to 4.2 prior to the I we found out that those |
| Dolovant Toot/Leberatory Date | | | 1 05 1 |
| Relevant Test/Laboratory Data | | | 1 of 1 |

| Relevant Test/Laboratory Data | | | | 1 of 1 |
|-------------------------------|-----------------------------|---------------|-----------------|--------------------|
| | Test Name | LEAD (VENOUS) | Test Date | 06-Oct-2023 |
| | Test Result | 4.2 | Test Unit | MICROGRAMS PER DEC |
| | Low Test Range | 0 | High Test Range | 3.5 |
| | More Information Available? | | | |

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es: 5

| Ac | Iditional Comments | | |
|----|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| Se | ection B - Product Availability | | |
| | Do you still have the product in case we need to evaluate it? | No | |
| | Do you have a picture of the 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 cinnamon fruit puree pouches | |
| | Name of the company that makes (or compounds) the product | WanaBana | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar | |
| | Strength | If Other | |
| | NDC number | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | | |
| | Did the problem return if the person started taking or using the product again? | Doesn't Apply | |
| Dr | ug Therapy | 1 of 1 | |
| | Expiration date | | |
| | Lot number | | |
| | Dosage Form | | |
| | Quantity | If Other | |
| | Frequency | If Other | |
| | How was it taken or used | If Other | |
| | Date the person first started taking or using the product | | _ |
| | Date the person stopped taking or using the product | | |
| | Date the person reduced dose of the product | | |

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| | Give best estimate of duration | 4 Month | |
|-----|---|---|--|
| | Is therapy still on-going? | | |
| W | ny was the person using the pr | roduct? (such as what condition was it supposed to treat) 1 of 1 | |
| | | | |
| | | | |
| | | | |
| | | | |
| | Returned to Manufacturer On | | |
| Se | ction D - About the Medical De | evice | |
| | Name of medical device | | |
| | Name of the company that | | |
| O+ | makes the medical device | a model catalog let social or LIDI number and the expiredian data if you can | |
| loc | ate them) | e model, catalog, lot, serial, or UDI number, and the expiration date, if you can | |
| | · | | |
| | | | |
| | | | |
| | | | |
| | Model Number | | |
| | Catalog Number | | |
| | Lot Number | | |
| | Serial Number | | |
| | UDDI Number | | |
| | Expiration date | | |
| | Was someone operating the | | |
| | medical device when the problem occurred? | | |
| Fo | r implanted medical devices C | NLY (such as pacemakers, breast implants, etc.) | |
| | ate the implant was put in | Date the implant was taken out (If | |
| | · · · | relevant) | |
| Se | ction E - About the Person Wh | no Had the Problem | |
| | Person's Initials | (b)(6) | |
| | Sex | Female | |
| | Gender | Cisgender woman/girl | |
| | Please Specify Other Gender | | |
| | Age (specify unit of time for age) | | |
| | Date of Birth | (b)(6) | |
| | Weight | 9.045 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 | |

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| LI | st known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) | |
|-----|--|----------|
| | | |
| | | |
| | | |
| PΙ | ease list all allergies (such as to drugs, foods, pollen or others) | |
| | | П |
| | | |
| | | |
| | | |
| Lis | st any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) | |
| | | |
| | | |
| | | |
| | | |
| Lis | st all current prescription medications and medical devices being used. | |
| | | |
| | | |
| | | |
| | | |
| Lis | st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. | |
| | | |
| | | |
| | | |
| | | |
| 186 | ection F - About the Person Filling Out This Form 1 of 1 | |
| | Primary? Yes | |
| | Reporter is Patient? | |
| | Title | |
| | Last name (b)(6) | \vdash |
| | Middle Name | |
| | First name | |
| | Number/Street (b)(6) | |
| | City | |
| | State/Province | Т |
| | Country UNITED STATES | |
| | ZIP or Postal code | |
| | Telephone number (b) (6) | |
| | Email address | |
| | Fax | |
| | Reporter Organization | |

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CTU No.: FDA-CDER-CTU-2023-83651 | Department: CFSAN | RCT No.: RCT-1179621 | CTU Triage Date: 14-Nov-2023 | Total Pag

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| Department | | |
|---|-------------|--|
| Reporter Speciality | | |
| Today's date | 13-Nov-2023 | |
| Did you report this problem to the company that makes the product (the manufacturer/compounder)? | | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | No | |

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CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag

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

| I Design Details | wii-us:uu) time zone | | |
|--|---|--|--------------------------|
| Basic Details | | | I |
| 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 | 14-Nov-2023 | CTU Received Date | 14-Nov-2023 |
| CTU Triage Date | | CTU Data Entry Date | |
| Report Type | Spontaneous | Report Classification | Drug |
| Assign To | User | | _ |
| User/Group | | | |
| Forward to Department | CDER (CDER-OSE-R | SS-CTU@fda.hhs.gov) (E2B) | |
| Case Priority | Direct | | |
| | <u> </u> | | |
| Contact | | | |
| Case First Name | Last Name | Email Address | Phone |
| Reporter (b)/6) | (b)(6) | (b)(C) | (la \ |
| (b)(6) | (b)(6) | (b)(6) | (b)(6) |
| | | | |
| Section A - About the Problem | | | |
| What kind of problem was it? (Check all that apply) Date the problem occurred | Used a product incorrectly wh Noticed a problem with the qu Had problems after switching 09-Nov-2023 | ffect (including new or worsening symptoms) ich could have or led to a problem ality of the product from one product maker to another maker | |
| What kind of problem was it? (Check all that apply) | Used a product incorrectly wh Noticed a problem with the qu Had problems after switching 09-Nov-2023 Yes Hospitalization - admitted or s Required help to prevent perm Disability or health problem Birth defect Life-threatening Death | ich could have or led to a problem ality of the product from one product maker to another maker | |
| What kind of problem was it? (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) Other serious/important medical | Used a product incorrectly wh Noticed a problem with the qu Had problems after switching 09-Nov-2023 Yes Hospitalization - admitted or s Required help to prevent perm Disability or health problem Birth defect Life-threatening Death | ich could have or led to a problem ality of the product from one product maker to another maker tayed longer nanent harm | |
| What kind of problem was it? (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) Other serious/important medical incident(Please Describe Below) | Used a product incorrectly wh Noticed a problem with the qu Had problems after switching: 09-Nov-2023 Yes Hospitalization - admitted or s Required help to prevent perm Disability or health problem Birth defect Life-threatening Death Other serious/important medic | ich could have or led to a problem ality of the product from one product maker to another maker tayed longer nanent harm tal incident(Please Describe Below) | nay reach out to you for |
| What kind of problem was it? (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) Other serious/important medical | Used a product incorrectly wh Noticed a problem with the qu Had problems after switching: 09-Nov-2023 Yes Hospitalization - admitted or s Required help to prevent perm Disability or health problem Birth defect Life-threatening Death Other serious/important medic | ich could have or led to a problem ality of the product from one product maker to another maker tayed longer nanent harm tal incident(Please Describe Below) | nay reach out to you for |
| What kind of problem was it? (Check all that apply) Date the problem occurred Serious Did any of the following happen? (Check all that apply) Other serious/important medical incident(Please Describe Below) 4.Tell us what happened and how | Used a product incorrectly when Noticed a problem with the question Had problems after switching 19-Nov-2023 Yes Hospitalization - admitted or selection Required help to prevent permediate Disability or health problem Birth defect Life-threatening Death Other serious/important mediculars | ich could have or led to a problem ality of the product from one product maker to another maker tayed longer nanent harm cal incident(Please Describe Below) | nay reach out to you for |

| Re | Relevant Test/Laboratory Data 1 of 1 | | | | |
|----|--------------------------------------|------------------|-----------------|----------------------|--|
| | Test Name | WHOLE BLOOD LEAD | Test Date | 09-Nov-2023 | |
| | Test Result | 13 | Test Unit | UNITS PER MILLILITRE | |
| | Low Test Range | 0 | High Test Range | 3 | |

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CTU No.: FDA-CDER-CTU-2023-83873 | Department: CFSAN | RCT No.: RCT-1179805 | CTU Triage Date: 14-Nov-2023 | Total Pag

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| | More Information Available? | | | | | | |
|----|---|---|-------------------------|---------|--|--|--|
| Ad | Additional Comments | | | | | | |
| | Pediatrician notified my wife and I | wife and I of the results. | | | | | |
| 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 | | <u></u> | | | |
| | Primary? | Yes | | | | | |
| | Туре | Drug/Biologic | | _ | | | |
| | This report is about | Food/Medical food | | | | | |
| | Name of the product as it appears on the box, bottle, or package (Include as many names as you see) | WanaBana Apple Cinnamo | WanaBana Apple Cinnamon | | | | |
| | Name of the company that makes (or compounds) the product | WanaBana | /anaBana | | | | |
| | Product Type(check all that apply) | Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generic Biosimilar | | | | | |
| | Strength | | If Other | | | | |
| | NDC number | | 1 | | | | |
| | Did the problem stop after the person reduced the dose or stopped taking or using the product? | | | | | | |
| | Did the problem return if the person started taking or using the product again? | | | | | | |
| 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 | 28-May-2023 | | | | | |
| | Date the person stopped taking | 04-Nov-2023 | | | | | |

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| | Date the person reduced dose of the product | | | | |
|-----------|---|---|---|-----------------------------|--|
| | Give best estimate of duration | | | | |
| | Is therapy still on-going? | | | | |
| W | ny was the person using the pr | roduct? (such as what co | ndition was it supposed to tr | reat) 1 of 1 | |
| | | | | | |
| | Returned to Manufacturer On | | | | |
| Se | ction D - About the Medical De | evice | | | |
| | Name of medical device | | | | |
| | Name of the company that makes the medical device | | | | |
| Ot loc | her identifying information (The ate them) | e model, catalog, lot, seri | al, or UDI number, and the e | expiration date, if you can | |
| | | | | | |
| | Model Number | | | | |
| | Catalog Number | | | | |
| | Lot Number | | | | |
| | Serial Number | | | | |
| | UDDI Number | | | | |
| | Expiration date | | | | |
| | Was someone operating the medical device when the problem occurred? | 1 | | | |
| Fo | r implanted medical devices C | NLY (such as pacemake | ers, breast implants, etc.) | | |
| Da | ate the implant was put in | | Date the implant was taken ou relevant) | ıt (If | |
| Se | ction E - About the Person Wh | no Had the Problem | | | |
| | Person's Initials | (b)(6) | | | |
| | Sex | Male | | | |
| | Gender | Cisgender man/boy | | | |
| | Please Specify Other Gender | | | | |
| | Age (specify unit of time for age) | 2 Year(s) | | | |
| | Date of Birth | | | | |
| | Weight | 11.7 kg | | | |
| | Ethnicity (Choose only one) | Not Hispanic/Latino | | | |
| | Race (Check all that apply) | American Indian or Alaska Nat Native Hawaiian or Other Paci Asian | | | |

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| | White Black or African American | | | | | | |
|-------|--|--|--|--|--|--|--|
| II ic | et known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) | | | | | | |
| | List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others) | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| PΙε | ease list all allergies (such as to drugs, foods, pollen or others) | | | | | | |
| | NKA | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Lis | t any other important information about the person (such as smoking, pregnancy, alcohol use, etc.) | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Lis | st all current prescription medications and medical devices being used. | | | | | | |
| | None | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Lis | st all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used. | | | | | | |
| | None | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Se | ection F - About the Person Filling Out This Form 1 of 1 | | | | | | |
| | Primary? Yes | | | | | | |
| | Reporter is Patient? | | | | | | |
| | Title | | | | | | |
| | Last name (b)(6) | | | | | | |
| | Middle Name | | | | | | |
| | First name / L / C / | | | | | | |
| | Number/Street (b)(6) | | | | | | |
| | | | | | | | |
| | State/Province | | | | | | |
| | Country UNITED STATES | | | | | | |
| | ZIP or Postal code | | | | | | |
| | Telephone number Email address (b)(6) | | | | | | |
| | Email address | | | | | | |

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es: 5

| Fax | | |
|---|-------------|--|
| Reporter Organization | | |
| Department | | |
| Reporter Speciality | | |
| Today's date | 14-Nov-2023 | |
| Did you report this problem to the company that makes the product (the manufacturer/compounder)? | No | |
| If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested): | No | |

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CTU No.: FDA-CDER-CTU-2023-84264 | Department: CFSAN | RCT No.: RCT-1180168 | CTU Triage Date: 16-Nov-2023 | Total Pag

| All dates displayed in the report are in EST(GMT-05:00) time zone Basic Details | | | | | | |
|---|--|--|---------------|--|--|--|
| Company Unit | CDER-CTU | Originating Account | FAERS | | | |
| Source Medium | MWO (Drug) | Source Form Type | E2B XML 3500B | | | |
| Priority | Routine | Coarco : crim :) pc | | | | |
| Override Auto Calculation Rule | No | | | | | |
| FDA Received Date | 15-Nov-2023 | CTU Received Date | 15-Nov-2023 | | | |
| CTU Triage Date | 10 1107 2020 | CTU Data Entry Date | 10 1101 2020 | | | |
| Report Type | Spontaneous | Report Classification | Drug | | | |
| Assign To | User State S | | | | | |
| User/Group | | | | | | |
| Forward to Department | | | | | | |
| Case Priority | | | | | | |
| Case Filolity | Direct | | | | | |
| | | | | | | |
| Contact | | | | | | |
| Case First Name Reporter | Last Name | Email Address | Phone | | | |
| (b)(6) | (b)(6) | (b)(6) | (b)(6) | | | |
| | (8)(8) | (10)(0) | (2)(3) | | | |
| Section A - About the Problem | | | | | | |
| What kind of problem was it? (Check all that apply) | Used a product incorrectly Noticed a problem with the | e effect (including new or worsening sympto which could have or led to a problem quality of the product ng from one product maker to another make | | | | |
| Date the problem occurred | 25-Oct-2023 | | | | | |
| Serious | Yes | | | | | |
| Did any of the following happen? (Check all that apply) | Required help to prevent per Disability or health problem Birth defect Life-threatening Death | ermanent harm | | | | |
| 4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for | | | | | | |
| any additional documents if necessary) | | | | | | |
| My son who is now 3 as of $(b)(6)$ lab results came back with high level of lead in his blood | | | | | | |
| | | | | | | |
| | | | | | | |

| Relevant Test/Laboratory Data | | | | 1 of 1 | |
|-------------------------------|----------------|----------------------|-----------------|------------------------------|--|
| | Test Name | LEAD BLOOD, CAPILLAR | Test Date | 31-Oct-2023 | |
| | Test Result | 12.8 | Test Unit | MICROGRAMS PER DEC ILITRE | |
| | Low Test Range | 3.5 | High Test Range | 5.0 | |

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