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INTRODUCTION

You have chosen to use this electronic portal to submit a voluntary report to FDA about an adverse event (an adverse health-related event, such as an illness or injury) associated with, and/or a product problem with, a food (to include dietary supplements and infant formula) or a cosmetic.

Please be advised that under 18 U.S.C. 1001, anyone making a materially false, fictitious or fraudulent statement to the U.S. Government is subject to criminal penalties.

The amount of time required to complete this report will vary depending on the information you have to provide. To submit this report, you must complete all required fields that are marked with a red asterisk.

Instructions for completing the MedWatch 3500 form, on which this report is based, can be found here.

Product packaging images are extremely helpful to FDA!

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2. Using your Mobile device, tap the "Open Camera" button in the Suspect Products Section to open your device camera.

Please enter a title to help you identify this report.*
Infant Formula Report

Did the food or product make someone sick, cause a negative reaction, or some other health problem?*
☑ Yes ☐ No

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?*
☐ Yes ☑ No

REPORTER INFORMATION

Do you wish to remain anonymous to the FDA?*
☐ Yes ☑ No

First Name: Riley
Last Name: Reporter
Email: Riley.Reporter@gmail.com
Confirm Email: Riley.Reporter@gmail.com
Primary Phone:
Mail/Zip Code*: 90210

What is your relationship to the person affected? The affected person is your:
Friend/Relative

Are you reporting as a member of a healthcare practice, law firm, company, consumer safety organization, a military unit, or other organization?
☐ Yes ☑ No

Are you a healthcare professional?
☐ Yes ☑ No

SUSPECT PRODUCT

Please use the section below to identify the product you believe was associated with the sickness, negative reaction, or other health problem.

Please scan the UPC code or enter the bar code number manually.
092685001003 Open Camera

Product Type*: Infant Formula
Product Brand: Company B
Product Name*: Formula X

Variety (Flavor, Scent, Etc.):

Package Type: Can
Package Size (Unit): 24 Ounces (oz)

Lot Code: LC789
Expiration / Use by date: 06/01/2019

What form is the infant formula?*
Powder

In preparation for feeding, what type of water was added the formula?
Bottled

What brand of bottled water was used?
ACME

Reason for Use
Supplemental nutrition

Does the product contain a warning or caution statement?
☐ Yes ☑ No

Was the product used more than once?
☐ Yes ☑ No

Date of use
11/23/2018

Were the directions for use on the product label followed?
☑ Yes ☐ No

Did the adverse event stop when product use stopped or amount consumed was reduced?
☑ Yes ☐ No

Have you reported the problem to the company on the label?
☐ Yes ☑ No

Was the affected individual using any other formulas, dietary supplements, or foods at the time of the adverse event that were not thought to be involved in the event?
☐ Yes ☑ No

AFFECTED PERSON

Gender*: Female
Weight(lbs): 15
Age at the time of event*: 6 month(s) old

Ethnicity:

Race
☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or other Pacific Islander

Does the affected individual have any food allergies?
☐ Yes ☑ No

Was the affected individual taking any medication at the time of the adverse event?
☐ Yes ☑ No

ADVERSE EVENT

Please use this section to tell us about the sickness, negative reaction, or other health problem.

Outcomes attributed to this adverse event

- ☐ Death
- ☐ A life-threatening experience
- ☐ Hospitalization—Initial or Prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Congenital Anomaly / Birth Defects
- ☐ Persistent or Significant Disability or Incapacity

Date adverse event began
11/23/2018

Please provide any additional details you can about the adverse event, including what led you to believe this product was associated with the adverse event
Daughter took 6 oz of prepared formula and immediately experienced vomiting, and was unable to keep anything down for 12 hours. She was finally able to keep down breast milk and seemed to recover.

SIGNS, SYMPTOMS, OR DIAGNOSES

Please specify any signs, symptoms, or diagnosis that the affected individual experienced.

Signs, symptoms, or diagnosis
Vomiting

How long after using the product did the symptom start?: 5 minute(s)
How long did the symptom last?: 12 hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?
☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☐ Yes ☐ No

Please click this icon for entering additional symptoms.

ATTACHMENT

Please attach any documentation you have about the adverse event. Medical records, lab results, or additional product images may all be helpful in FDA's review of the adverse event.

Document Type

Please click this icon for uploading additional attachment file.

OMB Burden Statement
Approval Number: 0910-00645
Expiration Date: XX/XX/20XX

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INTRODUCTION

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Please enter a title to help you identify this report.*
Food Report

Did the food or product make someone sick, cause a negative reaction, or some other health problem?*
☑ Yes ☐ No

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?*
☑ Yes ☐ No

REPORTER INFORMATION

Do you wish to remain anonymous to the FDA?*
☑ Yes ☐ No

Please provide any information you are comfortable sharing. All data may help FDA detect public health issues sooner.

Last Name
Withheld

Mail/Zip Code*
85472

What is your relationship to the person affected? The affected person is your:
Friend/Relative

Are you reporting as a member of a healthcare practice, law firm, company, consumer safety organization, a military unit, or other organization?
☐ Yes ☑ No

Are you a healthcare professional?
☐ Yes ☑ No

SUSPECT PRODUCT

Please use the section below to identify the product you believe was associated with the sickness, negative reaction, or other health problem.

Please scan the UPC code or enter the bar code number manually.
092685001003 Open Camera

Product Type* | Product Brand | Product Name*
Food | Company B | Food X

Variety (Flavor, Scent, Etc.)
Chicken

Package Type | Package Size (Unit)
Box | 4 | Ounces (oz)

Lot Code | Expiration / Use by date
LC789 | 06/01/2019

Is this a medical food?
☐ Yes ☑ No

Does the product contain a warning or caution statement?
☐ Yes ☑ No

Was the product consumed more than once?
☐ Yes ☑ No

Date of consumption
11/23/2018

After the food was purchased, how was it prepared?
Baked

Did the adverse event stop when product use stopped or amount consumed was reduced?
☑ Yes ☐ No

Have you reported the problem to the company on the label?
☐ Yes ☑ No

Was the affected individual using any other products, such as dietary supplements at the time of the adverse event that were not thought to be involved in the event?
☐ Yes ☑ No

AFFECTED PERSON

Gender* | Weight(lbs) | Age at the time of event*
Male | 75 | 10 | year(s) old

Ethnicity

Race
☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or other Pacific Islander

Does the affected individual have any food allergies?
☐ Yes ☑ No

Was the affected individual taking any medication at the time of the adverse event?
☐ Yes ☑ No

ADVERSE EVENT

Please use this section to tell us about the sickness, negative reaction, or other health problem.

Outcomes attributed to this adverse event

- ☐ Death
- ☐ A life-threatening experience
- ☐ Hospitalization—Initial or Prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Congenital Anomaly / Birth Defects
- ☐ Persistent or Significant Disability or Incapacity

Date adverse event began
11/23/2018

Please provide any additional details you can about the adverse event, including what led you to believe this product was associated with the adverse event
On 11/22 we baked a frozen chicken pot pie. My son had a piece, and 24 hours later began what looked like food poisoning. This is the only unusual thing we ate this week. Called the nurse line, and they advised ibuprofen for the fever and to visit the doctor if symptoms got worse. He cleared up the next day.

SIGNS, SYMPTOMS, OR DIAGNOSES

Please specify any signs, symptoms, or diagnosis that the affected individual experienced.

Signs, symptoms, or diagnosis
Fever

How long after using the product did the symptom start? | How long did the symptom last?
1 day(s) | 2 day(s)

If the affected individual received any treatment for the symptom, please describe:
Children's ibuprofen

Was the treatment directed by a healthcare professional?
☑ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☑ Yes ☐ No

Signs, symptoms, or diagnosis
Vomiting

How long after using the product did the symptom start? | How long did the symptom last?
1 day(s) | 1 day(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?
☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☐ Yes ☐ No

Please click this icon for entering additional symptoms.

ATTACHMENT

Please attach any documentation you have about the adverse event. Medical records, lab results, or additional product images may all be helpful in FDA's review of the adverse event.

Document Type

Please click this icon for uploading additional attachment file.

OMB Burden Statement
Approval Number: 0910-00645
Expiration Date: XX/XX/20XX

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Please enter a title to help you identify this report.*
Voluntary Dietary Supplement Report

Did the food or product make someone sick, cause a negative reaction, or some other health problem?*
☑ Yes ☐ No

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?*
☐ Yes ☑ No

REPORTER INFORMATION

Do you wish to remain anonymous to the FDA?*
☑ Yes ☐ No

Please provide any information you are comfortable sharing. All data may help FDA detect public health issues sooner.

Last Name
Withheld

Mail/Zip Code*
16865

What is your relationship to the person affected? The affected person is your:
I am the affected person

Are you reporting as a member of a healthcare practice, law firm, company, consumer safety organization, a military unit, or other organization?
☐ Yes ☑ No

Are you a healthcare professional?
☐ Yes ☑ No

SUSPECT PRODUCT

Please use the section below to identify the product you believe was associated with the sickness, negative reaction, or other health problem.

Please scan the UPC code or enter the bar code number manually.
092685001003 Open Camera

Product Type*	Product Brand	Product Name*
Dietary Supplement	Company B	Supplement X

Variety (Flavor, Scent, Etc.)

Product Strength (Unit)		Package Type	Package Size (Unit)	
100	Milligrams (mg)	Bottle	30	Tablets

Lot Code	Expiration / Use by date
LC789	06/01/2019

Reason for Use

Does the product contain a warning or caution statement?
☐ Yes ☑ No

Was the product used more than once?
☐ Yes ☑ No

Date of use
11/23/2018

Were the directions for use on the product label followed?
☑ Yes ☐ No

Did the adverse event stop when product use stopped or amount consumed was reduced?
☑ Yes ☐ No

Have you reported the problem to the company on the label?
☑ Yes ☐ No

Was the affected individual using any other Dietary Supplements at the time of the adverse event that were not thought to be involved in the event?
☐ Yes ☑ No

AFFECTED PERSON

Gender*	Weight(lbs)	Age at the time of event*	
Male	150	45	year(s) old

Ethnicity

Race
☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or other Pacific Islander

Does the affected individual have any food allergies?
☑ Yes ☐ No

Was the affected individual taking any medication at the time of the adverse event?
☑ Yes ☐ No

↳FOOD ALLERGIES

Please specify allergies the affected individual has, whether diagnosed or not:

Allergen Category:	Allergen:	Please select confirmation test method.
Shellfish, Crustacean	Shrimp	Skin Prick/Scratch Test

Please click this icon for entering additional allergy information.

↳MEDICATION

Please specify medications the affected individual was taking at the time of the event, and the conditions they were treating.

Medication Brand	Medication Name
Company C	Med X

Dose amount (Unit)		Frequency value (Unit)	
		1	time(s) per day

Condition being treated.
High blood pressure

Please click this icon for entering additional medication information.

ADVERSE EVENT

Please use this section to tell us about the sickness, negative reaction, or other health problem.

Outcomes attributed to this adverse event

- ☐ Death
- ☐ A life-threatening experience
- ☑ Hospitalization—Initial or Prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Congenital Anomaly / Birth Defects
- ☐ Persistent or Significant Disability or Incapacity

Date adverse event began
11/23/2018

Please provide any additional details you can about the adverse event, including what led you to believe this product was associated with the adverse event.
The adverse event began about an hour after I took the product. Nausea, dizziness, and difficulty breathing. I was admitted to the hospital overnight and released when my symptoms cleared up.

SIGNS, SYMPTOMS, OR DIAGNOSES

Please specify any signs, symptoms, or diagnosis that the affected individual experienced.

Signs, symptoms, or diagnosis
Nausea

How long after using the product did the symptom start?		How long did the symptom last?	
1	hour(s)	3	hour(s)

If the affected individual received any treatment for the symptom, please describe:
Anti-nausea medication in the ER

Was the treatment directed by a healthcare professional?
☑ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☑ Yes ☐ No

Signs, symptoms, or diagnosis
Dizziness

How long after using the product did the symptom start?		How long did the symptom last?	
1	hour(s)	3	hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?
☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☐ Yes ☐ No

Signs, symptoms, or diagnosis
Difficulty breathing

How long after using the product did the symptom start?		How long did the symptom last?	
1	hour(s)	3	hour(s)

If the affected individual received any treatment for the symptom, please describe:
Antihistamine

Was the treatment directed by a healthcare professional?
☐ Yes ☑ No

Did the treatment resolve or reduce the severity of the adverse event?
☑ Yes ☐ No

Please click this icon for entering additional symptoms.

ATTACHMENT

Please attach any documentation you have about the adverse event. Medical records, lab results, or additional product images may all be helpful in FDA's review of the adverse event.

Document Type

Please click this icon for uploading additional attachment file.

OMB Burden Statement
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INTRODUCTION

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Please enter a title to help you identify this report.*
Cosmetics Report

Did the food or product make someone sick, cause a negative reaction, or some other health problem?*
☑ Yes ☐ No

Was there a problem with the product (e.g., defect in the product such as an unusual odor, taste, or appearance)?*
☐ Yes ☑ No

REPORTER INFORMATION

Do you wish to remain anonymous to the FDA?*
☑ Yes ☐ No

Please provide any information you are comfortable sharing. All data may help FDA detect public health issues sooner.

Last Name
Withheld

Mail/Zip Code*
85472

What is your relationship to the person affected? The affected person is your:
Friend/Relative

Are you reporting as a member of a healthcare practice, law firm, company, consumer safety organization, a military unit, or other organization?
☐ Yes ☑ No

Are you a healthcare professional?
☐ Yes ☑ No

SUSPECT PRODUCT

Please use the section below to identify the product you believe was associated with the sickness, negative reaction, or other health problem.

Please scan the UPC code or enter the bar code number manually.
092685001003 Open Camera

Product Type*	Product Brand	Product Name*
Cosmetic	Company B	Cosmetic X

Variety (Flavor, Scent, Etc.)

Package Type	Package Size (Unit)	
Tube	65	Grams (g)

Lot Code
LC789

Does the product contain a warning or caution statement?
☐ Yes ☑ No

Was the product used more than once?
☐ Yes ☑ No

Date of use
06/01/2019

Were the directions for use on the product label followed?
☑ Yes ☐ No

Did the adverse event stop when product use stopped or amount consumed was reduced?
☑ Yes ☐ No

Have you reported the problem to the company on the label?
☐ Yes ☑ No

Was the affected individual using any other Cosmetics at the time of the adverse event that were not thought to be involved in the event?
☐ Yes ☑ No

AFFECTED PERSON

Gender*	Weight(lbs)	Age at the time of event*	
Female	125	32	year(s) old

Ethnicity

Race
☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or other Pacific Islander

Please specify skin conditions the affected person had before the event began
☐ Rosacea ☐ Psoriasis ☑ Eczema ☐ Other

Does the affected individual have any food allergies?
☐ Yes ☑ No

Was the affected individual taking any medication at the time of the adverse event?
☐ Yes ☑ No

ADVERSE EVENT

Please use this section to tell us about the sickness, negative reaction, or other health problem.

Outcomes attributed to this

- ☐ Death
- ☐ A life-threatening experience
- ☐ Hospitalization—Initial or Prolonged
- ☑ Other Serious (Important Medical Events)
- ☐ Congenital Anomaly / Birth Defects
- ☐ Persistent or Significant Disability or Incapacity

Date adverse event began
11/23/2018

Please provide any additional details you can about the adverse event, including what led you to believe this product was associated with the adverse event
Applied foundation and it caused an itchy, red rash that lasted for a day.

In which part of the body did the reaction develop?
☐ Lips ☑ Face ☐ Hair ☐ Eyes ☐ Underarms ☐ Nails ☐ Respiratory system ☐ Other

SIGNS, SYMPTOMS, OR DIAGNOSES

Please specify any signs, symptoms, or diagnosis that the affected individual experienced.

Signs, symptoms, or diagnosis
Rash

How long after using the product did the symptom start?		How long did the symptom last?	
5	minute(s)	24	hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?
☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?
☐ Yes ☐ No

Please click this icon for entering additional symptoms.

ATTACHMENT

Please attach any documentation you have about the adverse event. Medical records, lab results, or additional product images may all be helpful in FDA's review of the adverse event.

Document Type

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Riley Reporter

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- Initial Reporter Information
- Affected Individual Information
- ↳Medications
- Adverse Event/Product Problem Description
- ↳Signs, Symptoms, or Diagnoses
- Suspect Product
- Attachment

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FILE INFORMATION

SupplementX ...

TXT

INTRODUCTION

You have chosen to use this portal to submit a mandatory serious adverse event report about a dietary supplement to the FDA as required under section 761 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379aa-1). Manufacturers, packers, or distributors of dietary supplements whose names appear on the label of a dietary supplement marketed in the United States are required to submit to FDA on the MedWatch form any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement. Serious adverse event reports received through the address or phone number on the label of a dietary supplement, as well as all follow-up reports of new medical information received by the responsible person within one year after the initial report, must be submitted to FDA no later than 15 business days after the report is received by the responsible person.

FDA has made available, for those who chose to use it, this method of electronic submission for mandatory serious adverse event reports about a dietary supplement. FDA will accept reports filed via this portal to satisfy the firms' statutory reporting duty under section 761 of the FD&C Act provided that the responsible person has completed all required fields in and submitted this electronic form. Use of this electronic version of the MedWatch form is completely voluntary and the paper MedWatch form 3500A will continue to be accepted until FDA conducts rule making to require use of an electronic form for mandatory reports. Instructions for completing the MedWatch 3500A form, on which this report is based, can be found here, and instructions specific to using the MedWatch 3500A form for mandatory dietary supplement serious adverse event reports can be found here. Additionally, FDA has published industry guidance for submitting dietary supplement serious adverse event reports. This document can be found here.

REPORT IDENTIFYING INFORMATION

Please enter a title to help you identify this report. Consider using your firm's internal case tracking number for simplified recordkeeping. *

Product A Mandatory Report

In addition to the serious adverse event, did the initial reporter also notice a product problem (e.g., defect in the product such as a bad odor, bad taste, or unusual appearance)?*

☐ Yes ☑ No

Enter the date you received the initial report*

11/28/2018

SITE POINT OF CONTACT INFORMATION

Please provide the contact information of someone at the manufacturer's, packer's, or distributor's organization in the event that FDA follow-up is necessary.

First Name: Riley
Last Name: Reporter
Email: Riley.Reporter@company.com
Confirm Email: Riley.Reporter@company.com
Primary Phone Number: 555-555-5555

MANUFACTURER, PACKER, OR DISTRIBUTOR SITE INFORMATION

Organization Name*: Company B
Street Address line 1*: 100 Main Street
Street Address line 2:
City/Town*: New York
State*: New York
Mail/Zip Code*: 10024
Country*: United States

INITIAL REPORTER INFORMATION

Please provide the contact information for the Initial Reporter. The initial reporter is the person who notified you, the responsible party, of the serious adverse event. In order to provide a complete report, you must provide an identifier for the initial reporter or state that they wish to remain anonymous. Acceptable identifiers are explained in [section 13 of the guidance].

Does the initial reporter wish to remain anonymous to the FDA?*

☑ Yes ☐ No

Last Name: Withheld

Was the initial reporter a healthcare professional? ☑ Yes ☐ No

Healthcare professional type: Physician

Did the initial reporter indicate that they also reported the event to the FDA?*

☐ Yes ☑ No

AFFECTED INDIVIDUAL INFORMATION

Patient Identifier*: ABC

Gender: Male
Weight(lbs): 150
Age at the time of event: 45 year(s) old

Ethnicity: Not Reported

Race

☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or other Pacific Islander

Was the affected individual reported to have any food allergies?

☐ Yes ☑ No

Was the affected individual taking any medication at the time of the adverse event?

☑ Yes ☐ No

↳MEDICATIONS

Please specify medications the affected individual was taking at the time of the event, and the conditions they were treating.

Medication Brand: Company C
Medication Name: Med X
Dose amount (Unit):
Frequency value (Unit):

What condition was this medication treating?

Hypertension

Please click this icon for entering additional medication information.

ADVERSE EVENT/PRODUCT PROBLEM DESCRIPTION

Outcomes attributed to this adverse event*

- ☐ Death
- ☐ A life-threatening experience
- ☑ Hospitalization—Initial or Prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Congenital Anomaly / Birth Defects
- ☐ Persistent or Significant Disability or Incapacity

Date adverse event began: 11/23/2018

Please provide any additional details about the adverse event *

Patient took Supplement X according to directions and experienced dizziness, nausea, and difficulty breathing. Patient was admitted to hospital.

Was the affected individual using any other dietary supplements or medical devices at the time of the event that were not thought by the initial reporter to be involved in the event?

☐ Yes ☑ No

↳SIGNS, SYMPTOMS, OR DIAGNOSES

Please specify any signs, symptoms, or diagnosis that the initial reporter described.

Signs, symptoms, or diagnosis: NAUSEA
How long did the symptom last?: 2 hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?

☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?

☐ Yes ☐ No

Signs, symptoms, or diagnosis: DIZZINESS
How long did the symptom last?: 1 hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?

☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?

☐ Yes ☐ No

Signs, symptoms, or diagnosis: DYSPNOEA
How long did the symptom last?: 1 hour(s)

If the affected individual received any treatment for the symptom, please describe:

Was the treatment directed by a healthcare professional?

☐ Yes ☐ No

Did the treatment resolve or reduce the severity of the adverse event?

☐ Yes ☐ No

Please click this icon for entering additional symptoms.

SUSPECT PRODUCT

For adverse event reporting, a suspect product is one that the initial reporter suspected was associated with the adverse event.

Please scan the UPC code or enter the bar code number manually.

892685001003 Open Camera

Product Brand: Company B
Product Name*: Supplement X
Variety (Flavor, Scent, Etc.):
Product Strength (Unit):
Diagnosis or Reason for Use:
Lot Code: LC789
Expiration / Use by date: 06/01/2019

As required by 761(b)(1) of the FD&C Act (21 U.S.C. 379aa - 1(b)(1)) you must submit a copy of the product label. Please upload the label image below:*

SupplementX Label.txt

Was the product used more than once?

☐ Yes ☑ No

Date of use: 11/23/2018

Were the directions for use on the product label followed?

☑ Yes ☐ No

Did the event stop when product use stopped or amount consumed was reduced?

☑ Yes ☐ No

Please click this icon for entering additional suspect product information.

ATTACHMENT

Please attach any documentation you have about the adverse event. Medical records, lab results, or additional product images may all be helpful in FDA's review of the adverse event.

Document Type:

Please click this icon for uploading additional attachment file.

OMB Approval Number: 0910-00645
Expiration Date: XX/XX/20xx
Burden Statement

Confirm Report | Upload Photo | Save Report