

- Begin a Voluntary Report NEW
- Introduction
- Reporter Information
- Suspect Product
- Affected Person
- Allergies
- Adverse Event
- Signs, Symptoms, or Diagnoses
- Attachment

Confirm Report Upload Photo

### 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!*

*There are two ways to attach images to this report:*

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- 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

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.

- Begin a Voluntary Report NEW
- Introduction
- Reporter Information
- Suspect Product
- Affected Person
- Adverse Event
- Signs, Symptoms, or Diagnoses
- Product Problem Description
- Attachment

Confirm Report Upload Photo

### 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

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.

- Begin a Voluntary Report NEW
- Introduction
- Reporter Information
- Suspect Product
- Affected Person
- Food Allergies
- Medication
- Adverse Event
- Signs, Symptoms, or Diagnoses
- Attachment

Confirm Report | Upload Photo

### INTRODUCTION

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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

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

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Document Type

Please click this icon for uploading additional attachment file.

- Begin a Voluntary Report NEW
- Introduction
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- Adverse Event
- Signs, Symptoms, or Diagnoses
- Attachment

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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

Product Type\*  
 Cosmetic

Product Brand  
 Company B

Product Name\*  
 Cosmetic X

Variety (Flavor, Scent, Etc.)

Package Type  
 Tube

Package Size (Unit)  
 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\*  
 Female

Weight(lbs)  
 125

Age at the time of event\*  
 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?  
 5 minute(s)

How long did the symptom last?  
 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

Please click this icon for uploading additional attachment file.



- Begin a Mandated Dietary Supplement Report NEW
Introduction
Report Identifying Information
Site Point of Contact Information
Manufacturer, Packer, or Distributor Site Information
Initial Reporter Information
Affected Individual Information
Medications
Adverse Event/Product Problem Description
Signs, Symptoms, or Diagnoses
Suspect Product
Attachment

Confirm Report Upload Photo Save Report

FILE INFORMATION
SupplementX...
[Image of SupplementX.txt file]

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).

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

MANUFACTURER, PACKER, OR DISTRIBUTOR SITE INFORMATION
Organization Name\*
Company B
Street Address line 1\* Street Address line 2
100 Main Street
City/Town\* State\* Mail/Zip Code\*
New York New York 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? Healthcare professional type
[ ] Yes [ ] No Physician
Did the initial reporter indicate that they also reported the event to the FDA?
[ ] Yes [ ] No

AFFECTED INDIVIDUAL INFORMATION
Patient Identifier\*
ABC
Gender Weight(lbs) Age at the time of event
Male 150 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 Medication Name
Company C 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 How long did the symptom last?
NAUSEA 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 How long did the symptom last?
DIZZINESS 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 How long did the symptom last?
DYSPNOEA 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
Product Brand Product Name\*
Company B Supplement X
Variety (Flavor, Scent, Etc.)
Product Strength (Unit)
Diagnosis or Reason for Use
Lot Code Expiration / Use by date
LC789 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
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Document Type
Please click this icon for uploading additional attachment file.