

Draft Foods RQ for FDA Safety Reporting Portal



Welcome Guest

**Name:** Food Report

**ID:** 36730 (I)

**Created:** 7/1/2015

• **Introduction**

• Contact Information

• Person Affected

• Problem Summary

• Suspect Product Details

• Attachments

**OMB Approval**

**Number:** 0910-0645

**OMB Expiration**

**Date:** 4/30/2016

[OMB Burden Statement](#)

## Introduction

**\* = Required**

You have chosen to use this electronic portal to submit a voluntary product (adverse health-related event, such as an illness or injury) :

Please be advised that under 18 U.S.C. 1001, anyone making a material false statement is subject to criminal penalties.

This report has up to 4 sections. After you answer the questions on this report, the amount of time required to complete this report will vary depending on the number of your responses are automatically saved. To submit this report, you must click the Submit Report button.

Instructions for completing the MedWatch 3500 form, on which this report is based, are available at [www.fda.gov/medwatch](#).

### Report Identifying Information

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

**\* What type of report are you submitting?**

**\* What kind of product do you need to report about?**

Exit

Submit Report



# Reporting Portal

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report to FDA about an adverse event associated with a cosmetic and/or a product problem with a cosmetic product.

erially false, fictitious or fraudulent statement to the U.S. Government

this page, you may complete the other pages in any order. The  
ing on the information you have to provide. As you complete each page,  
must complete all required fields that are marked with a red asterisk.

is report is based, can be found [here](#).



- Adverse event (an adverse health-related event associated with the product)
- Product Problem (e.g., defects in the quality or safety of a product)
- Other
- Dietary Supplement
- Food
- Cosmetic
- Infant Formula



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## Contact Information

\* = Required

### Affected Individual Information

**Do you wish to remain anonymous to the FDA?**

**First Name**

**Last Name**

**Email**

**Confirm Email**

**Phone**

**Country**

**Street address line 1**

**Street address line 2**

**City/Town**

**State**

**Mail/Zip Code**

**Have you reported the event to the company on the label?**

**Are you a healthcare professional?**

**Healthcare professional type**

**If other, please describe**



Exit

Submit Report



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Yes

Please select ▼

Please select ▼

Manufacturer  
Distributor  
Other

Yes

Please select V

<--- Dependent on pr

vious question





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## Person Affected

\* = Required

### Affected Individual Information

Person's Initials

Gender

Age at time of event, *if unknown, please enter Date of birth below*

Date of birth

Weight

Race

Diagnosed allergies (*select all that apply*)

Relevant medical history

Exit

Submit Report





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male  female

- 
- Allergy
- Allergy Z
- Allergy Z1
- Allergy Z2





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## Problem Summary

### Adverse Event and/ or Product Problem

Date of adverse event

Duration of adverse event

How soon did the symptoms develop after using the product?

\* Outcomes attributed to adverse event (check all that apply)

If other, please describe:

Please select any of the symptoms below that you experienced

- |                                    |   |                          |
|------------------------------------|---|--------------------------|
| <input type="checkbox"/> Diarrhoea | <input type="checkbox"/> Choking        | <input type="checkbox"/> |
| <input type="checkbox"/> Vomiting  | <input type="checkbox"/> Abdominal Pain | <input type="checkbox"/> |
| <input type="checkbox"/> Nausea    | <input type="checkbox"/> Headache       | <input type="checkbox"/> |

How soon did symptoms develop after using the product?

\* Please provide details about the event or problem

Do you suspect certain ingredients in the product of the adverse event?

Which ingredient(s)?

Did all of the symptoms go away?

If so, how and when was it resolved?

**Date of lab test**

Add

Edit

Delete

At the end of this report you will be asked to provide information on the outcome of the case. This information is very important to us. We ask that you provide as much detail as possible.

Exit

Submit Report

**Adverse Event Term(s)**

Add

Edit

Delete



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## Description

Select unit of measure

the product?

Select unit of measure

All that apply)

- Hospitalization
- Disability/health problem
- Life-threatening (ex. breathing difficulties, anaphylactice shock, etc.)
- Death
  - Date of Death
- Other serious/important medical outcomes

What symptoms were experienced as a result of this event:

- Nausea
- Dyspnea (shortness of breath)
- Dysphagia (difficulty swallowing)
- 

- Dizziness
- Rash
- Pain
- 

the product?

Select unit of measure

Comments

---

: may have been the cause

Yes

Yes

Lab Test Name	Test Result(s)
Click on the <b>Add</b> button to add an item	

**Attention**

Provide attachments including photos relevant to this case. Being able to correctly identify the product in your report you please submit photos of all sides of your product (including the ingredients label and lot number).

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---

Click on the <b>Add</b> button to add an item
---







**Relevant Test/ Laboratory Data**

**Please provide any relevant lab test results.**

Consider attaching your lab documentation to this report, which you can do in

\*Lab test name

Date of lab test

Test Results

the final section.

v

Save

Cancel



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## Suspect Product(s) Details

\* = Required

For adverse event reporting, a suspect product is or

### \* Product Details

Name	Manufacturer/d	
Click on		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

### Product Ingredients

Ingredient	Amount	
Click on		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>



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ne that you, the reporter, suspect was associated with the adverse event.

<b>distributor/packer</b>	<b>UOM</b>
the <b>Add</b> button to add an item	

	<b>UOM</b>
the <b>Add</b> button to add an item	

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## Suspect Product Details

Please start typing the brand or name of the product in the "Select full name of product as it appears on the package label" field. The form will display all of the products with that name or brand in the drop down box menu below. If your product is not displayed, please choose "other".

\* Select full name of product as it appears on the package label

\* Do you need to change any of the pre-filled product information below?

 es 

\* Full name of product as it appears on the package label

Product manufacturer, packer, distributor

UPC Code

Expiration/use-by date

Lot number

Is this a medical food?

 's 

Diagnosis or Reason for Use

## Product Usage

Dates of product use (estimate if necessary) if dates are unknown, please estimate duration of use below. Start:

End:

Duration of product use

Frequency of usage

Amount consumed per serving

How was the product prepared?

Did the problem stop after reduced does or usage?

Yes

Did the problem return if product was used again?

Yes  No

Additional Notes Describing Product Usage

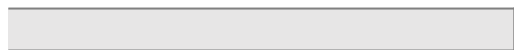
---

---





ackage label" box.  
oduct is not

<--- Display based on "Is this a medical food?"

Empty rectangular box for input.

Save

Cancel

**Suspect Product Ingredient**

**Ingredient**

Please select

**Ingredient Amount**

A rectangular dialog box with a thin black border. At the top is a solid olive-green horizontal bar. Below it are two empty rectangular input fields. At the bottom are two buttons: "Save" on the left and "Cancel" on the right, both with a light gray background and black text.



Welcome Guest

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## Concomitant Product(s) Detail

\* = Required

For adverse event reporting, a suspect product is or

### \* Product Details

Name	Manufacturer/d
Click on	
<input type="button" value="Add"/>	<input type="button" value="Edit"/>
<input type="button" value="Delete"/>	

### Product Ingredients

Ingredient	Amount
Click on	
<input type="button" value="Add"/>	<input type="button" value="Edit"/>
<input type="button" value="Delete"/>	

**No Concomitant products for foods i**



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Is

ne that you, the reporter, suspect was associated with the adverse event.

<b>distributor/packer</b>	<b>UOM</b>
the <b>Add</b> button to add an item	

	<b>UOM</b>
the <b>Add</b> button to add an item	

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reports



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## Important Notice

At

You have now reached the end of this report. On the next page you will be taken to this case. Being able to correctly identify the product in your case is critical. You must provide information on **all** sides of your product (including the ingredients label and lot number) and your reaction (including laboratory/medical examinations, photo of your reaction, etc.).

Please click **Next** to proceed to the Attachments section of the report.

Exit

Submit Report



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## Attention

will be asked to provide attachments, including photos relevant  
e is very important to us. We ask that you please submit photos  
number). Additionally, please submit any other relevant attachments  
, etc.).

ort.

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## Attachments

**\* = Required**

You may upload up to 5 (10 MB each) attachments per submission.  
.doc, .docx, .pdf, .gif, .jpg, .jpeg, .png, .tif, .tiff, .txt, .rtf, .xls, .xlsx, .v

### File Name

Click on

Add

Edit

Delete

Exit

Submit Report

The following file extensions are permitted:  
vpd

Type	Description
	the <b>Add</b> button to add an item

**Relevant Test/ Laboratory Data**

\* File to attach

\* Description of Attachment

\* Type of Attachment

