

Draft Infant Formula RQ for FDA Safety Reporting Portal



Welcome Guest

Name: Dietary Supp. Report

ID: 36730 (I)

Created: 7/1/2015

• **Introduction**

• Contact Information

• Person Affected

• Problem Summary

• Suspect Product Details

• Concomitant 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

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

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 cosmetic product)
- Other
- Dietary Supplement
- Food
- Cosmetic
- Infant Formula



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[OMB Burden Statement](#)

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 any of the following?

Are you a healthcare professional?

Healthcare professional type

If other, please describe

Exit

Submit Report



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)



Yes

Please select ▼

Please select ▼

- Manufacturer
- Distributor
- Packer

Yes

Please select v

<--- Dependent on pri

< BackNext >

evious question



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OMB Approval

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[OMB Burden Statement](#)

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



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)



Male Female

- Allergy X
- Parent Allergy Y
- Child Allergy 1
- Child Allergy 2
- Allergy Z

^

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< Back

Next >



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[OMB Burden Statement](#)

Problem Summary

Adverse Event and/ or Product Problem

Date of adverse event

Duration of adverse event

* 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"/> Coughing | <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"/> |

Please describe the event or problem

Do you suspect certain ingredients in the product cause 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 details on how the case is very important to us. We ask that

Exit

Submit Report



Safety Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

Description

Select unit of measure

Other conditions that apply)

- Inpatient Hospitalization
- Disability/health problem
- Disfigurement
- Life-threatening (ex. breathing difficulties, anaphylactice shock, etc.)
- Death

Date of Death

- Other serious/important medical outcomes

Other symptoms experienced as a result of this event:

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

- Dizziness
- Rash
- Pain

: may have been the

es

es

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

Attention

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

< Back

Next >

<--- Based on check box

Relevant Test/ Laboratory Data

* Lab test name

Please select

Date of lab test

Test Results



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OMB Expiration

[OMB Burden Statement](#)

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"/>	



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

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

istributor/packer	UOM
the Add button to add an item	

<--- Note no ingredier

[< Back](#) [Next >](#)

nts for IF

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

What form is the product?

Is this a specialized product for something other than, or in addition too, general nutrition?

 ^{es}

Diagnosis or Reason for Use

Product available for evaluation by FDA?

 ^{es}

Product Usage

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

End:

Frequency of usage

Amount consumed per serving

What type of water was used to prepare the product?

Did the problem stop after reduced does or usage?

 :s

Did the problem return if product was used again?

 :s ~

package label" box.
product is not

<--- Free Text and Auto Fill

<--- Auto Fill

<--- Auto Fill

<--- Powder, Ready to Serve, Concentrate

<--- Show/Hide based on preceding question

○

 V

Select unit of measure **V**

<--- Tap, Bottled, Distilled, etc

Save

Cancel

No Ingredients for IF



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OMB Approval

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OMB Expiration

Date: 4/30/2016

[OMB Burden Statement](#)

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"/>

Exit

Submit Report



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

Is

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distributor/packer	UOM
the Add button to add an item	

<--- Note no ingredier

< Back Next >

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 ^{es}

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Amount consumed per serving

Did the problem stop after reduced does or usage?

 ^s

Did the problem return if product was used again?

Yes

No



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oduct is not



<--- Based on answer to previous question

Save

Cancel



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- Product(s) Details
- Problem Summary
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- Attachments

OMB Approval

Number: 0910-0645

OMB Expiration

Date: 4/30/2016

[OMB Burden Statement](#)

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. Please provide **all** sides of your product (including the ingredients label and lot number) and photos (including laboratory/medical examinations, photo of your reaction, etc.)

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

Exit

Submit Report



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

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
(e.g., photos, etc.).

ort.

[< Back](#)

[Next >](#)



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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



Reporting Portal

[HOME](#) [FAQS](#) [RELATED LINKS](#) [CONTACT US](#) [FEEDBACK](#) [HELP](#)

The following file extensions are permitted:
vpd

Type	Description
	the Add button to add an item

Relevant Test/ Laboratory Data

* File to attach

* Description of Attachment

* Type of Attachment

