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) a

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

This report has up to 4 sections. After you answer the questions on amount of time required to complete this report will vary dependir your responses are automatically saved. To submit this report, you

Instructions for completing the MedWatch 3500 form, on which thi

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

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
ng 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)
- ○ th
- ○ 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 any of the following?

Are you a healthcare professional? ○

Healthcare professional type

If other, please describe

Exit | Submit Report

HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP

)Yes ○ o

Please select V

Please select V

☐ Manufacturer
☐ Distributor
☐ Packer

)'es ○ ɔ

Please select V

<--- Dependent on pr

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evious 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

HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP

Male Female

Select unit of measure

Select unit of measure

Select one

- [ ] Allery X
- [ ] Parent Allergy Y
- [ ] Child Allergy 1
- [ ] Child Allergy 2
- [ ] Allergy Z

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Problem Summary

Adverse Event and/ or Product Problem

Date of adverse event

Duration of adverse event

*** Outcomes attributed to adverse event (check al**

If other, please describe:

Please select any of the symptoms below that yo

☐ iarrhoea	☐ oking	
☐ omiting	☐ odominal Pain	
☐ lausea	☐ eadache	

Please describe the ever.. 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 pr
case is very important to us. We ask that

Exit | Submit Report

n Description

Select unit of measure

ll that apply)

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

u experienced as a result of this event:

- ☐ Malaise
- ☐ Dysponea (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

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

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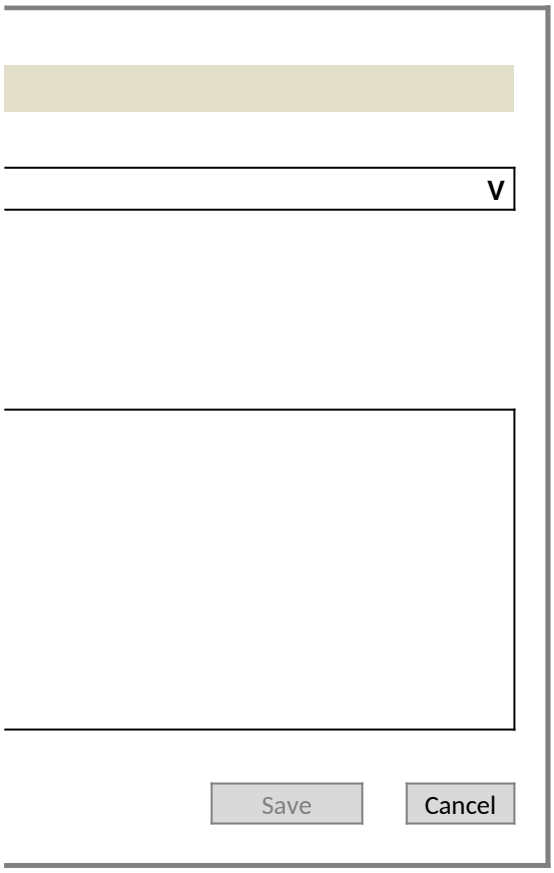
<--- Based on check box

Relevant Test/ Laboratory Data

*Lab test name: Please select

Date of lab test:

Test Results:


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

Add | Edit | Delete

Exit | Submit Report

HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP

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

listributor/packer	UOM
the **Add** button to add an item	

<--- Note no ingredier

< Back Next >

ıts 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 p
The form will display all of the products with that name or brand in the drop down box menu below. If your pro
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? Select one

Did the problem stop after reduced does or usage? ○ Yes ○ No

Did the problem return if product was used again? ○ Yes ○ No

ackage label" box.
oduct is not

<--- Free Text and Auto Fill

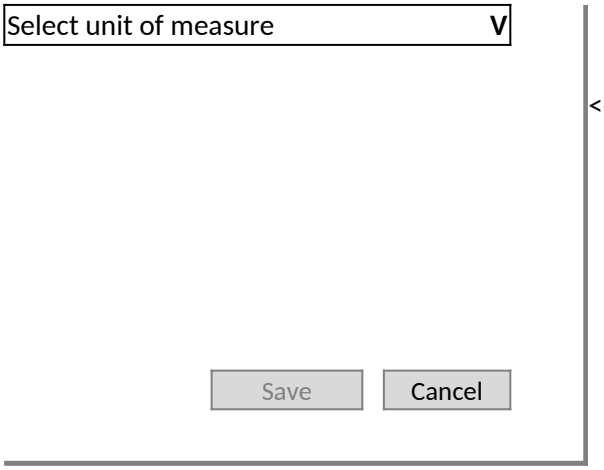
<--- Auto Fill

<--- Auto Fill

<--- Powder, Ready to Serve, Concentrate

<--- Show/Hide based on preceding question

Select unit of measure V



<--- Tap, Bottled, Distilled, etc

No Ingredients for IF

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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

Add | Edit | Delete

Exit | Submit Report

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○ Yes ○ No

ackage label" box.
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<--- Based on answer to previous question

Select unit of measure V

Select unit of measure V


Save
Cancel

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Important Notice

At

You have now reached the end of this report. On the next page you
to this case. Being able to correctly identify the product in your cas
of **all** sides of your product (including the ingredients label and lot r
(including laboratory/medical examinations, photo of your reactio

Please click **Next** to proceed to the Attachments section of the repo

Exit | Submit Report

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tention

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
n, etc.).

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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, .w

File Name
Click on

Add | Edit | Delete

Exit | Submit Report

The following file extensions are permitted:

vpd

Type	Description
the **Add** button to add an item	

< Back Next >

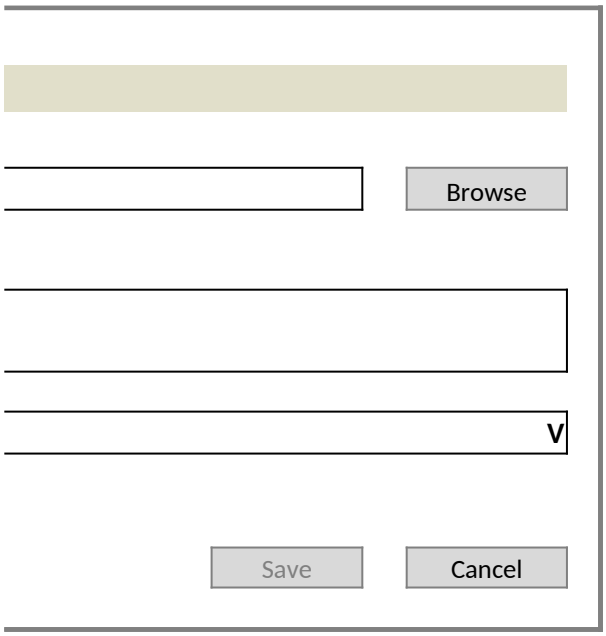
Relevant Test/ Laboratory Data

*File to attach

* Description of Attachment

* Type of Attachment

Please select


Browse
Save
Cancel