Draft Infant Formula RQ for FDA Safety Reporting Portal



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 1g 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.

0	Iverse event (an adverse health-related event sociated with the product)
0	Product Problem (e.g., defects in the quality or safety of a cosmetic product)
0	th
0 0 0	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?

C

First Name

Last Name

Email

Confirm Email

Phone

Country

Street address line 1

Street address line 2

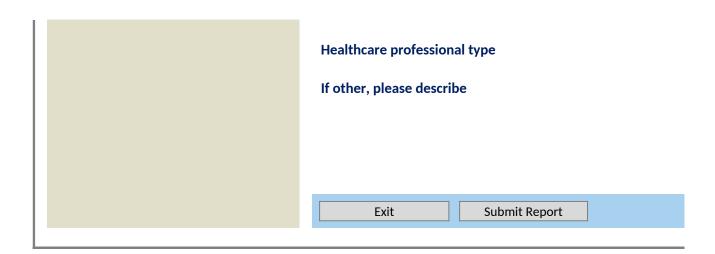
City/Town

State

Mail/Zip Code

Have you reported the event to any of the following?

Are you a healthcare professional?





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Nease select	V
Please select	V
<u> </u>	
Please select	V
☐ Manufacturer	
☐ Distributor	
☐ Packer	
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evious question



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Person Affected

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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



O ^{1ale} O nale		
	Select unit of measure	V
	Select unit of measure	V
Select one	V	
☐ Allery X ☐ Parent Allergy Y		
☐		
hild Allergy 2 Allergy Z		
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		v



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Problem Summary

Adverse Event and/ or Product Problem

Date of adverse event

Duration of adverse event

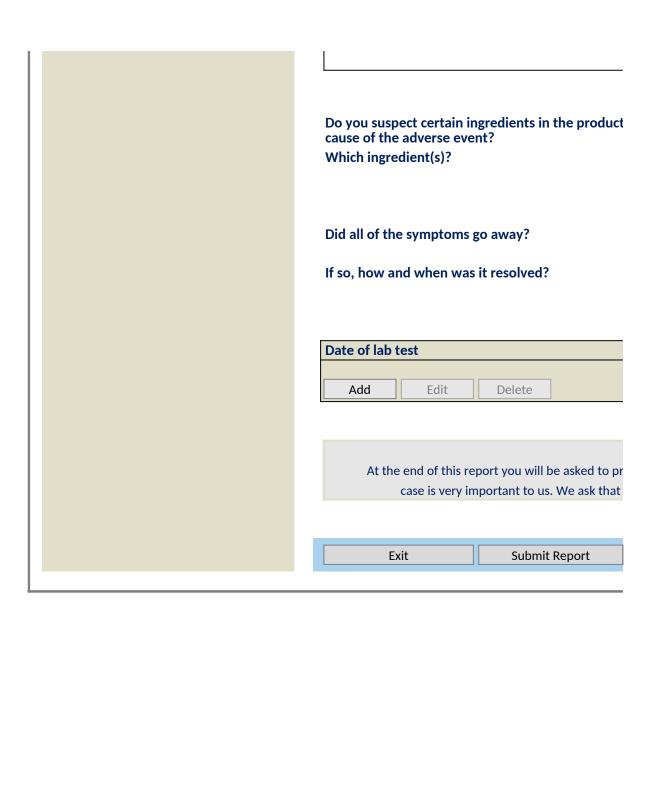
* Outcomes attributed to adverse event (check a

If other, please describe:

Please select any of the symptoms below that you

iarrhoea (joking [omiting / pdominal Pain [ausea | leadache [

Please describe the ever or problem





Description		
	Select unit of measure	V
l 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 thi	s event:	
∕lalaise)ysponea (shortness of breath) ¬ysphagia (difficulty swallowing)	Dizziness Rash Pain	

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	· ·		
○ ∋s	Ο		
		Test Result(s)	
n item			
sides of your produ	ıct (including the	ingredients label a	and lot number).
			< Back Next >
	an item	an item otos relevant to this case. Being able	Test Result(s)

<--- 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



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

listributor/packer	UOM
the Add button to add an item	

<--- Note no ingredier

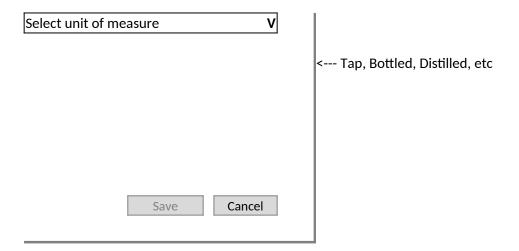
< Back



Suspect Product Details			
Please start typing the brand or name of the product in the "Select full nar The form will display all of the products with that name or brand in the dro			
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?	Oes	0	
* 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?	O ^{es}	0	
Diagnosis or Reason for Use			
Product available for evaluation by FDA?	Oes	0	0
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 on	e	V
Did the problem stop after reduced does or usage?	○ ·s	0	
Did the problem return if product was used again?	○ ¹s	0	

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
0	
Select unit of measure V	



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



Is

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listributor/packer	UOM
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<--- Note no ingredier

< Back Next >



Please start typing the brand or name of the product in the "Select full na The form will display all of the products with that name or brand in the dr 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?	O ^{es}	0
* 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 specialized product for something other than, or in addition too, general nutrition?	O ^{es}	0
Diagnosis or Reason for Use		
Product Usage		
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End:		
Frequency of usage		
Amount consumed per serving		
Did the problem stop after reduced does or usage?	⊖ ·s	0

Did the problem return if product was used again?	○ ·s	0	

	1
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	< Based on answer to previous question
Coloct unit of massure	
Select unit of measure V	
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Select unit of measure V	
	I .

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 case of **all** sides of your product (including the ingredients label and lot r (including laboratory/medical examinations, photo of your reaction

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

Exit

Submit Report



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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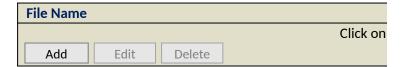
Date: 4/30/2016

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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



Exit Submit Report



The following file extensions are permitted: vpd

Туре	Description
the Add button to add an item	

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Relevant Test/ Laboratory Data	
*File to attach	
The to attach	
* Description of Attachment	
* Type of Attachment	Please select

	Browse
	V
Save	Cancel