

## The Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

## Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- Drug Manufacturers
- Dietary supplement manufacturers, packers, and distributors

Others, including concerned citizens, health professionals, and public health officials, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

Learn more about mandatory and voluntary reporting

## Begin Reporting Here

### 1. Login

Email

Password

Or

[Forgot your password?](#)

Remember me

Login

### 2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Report as

### Account Benefits

- Save a draft
- Easy follow up
- View submissions
- Fast data entry

Create

## Reports You Can Submit Through this Portal

FDA safety issues involving:

- Human or animal reportable foods
- Animal drugs
- Pet foods
- Tobacco Products
- Dietary Supplements

NIH safety issues involving:

- NIH gene-transfer research

For other issues, find out where to submit your report.

## Account Registration

\*=Required

\* Which of the following best describes you?

- A food facility or responsible party that manufactures, processes, packs, or holds food who is submitting a reportable food report.
- A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food
- A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving pet food
- A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving pet food
- A marketing authorization holder (manufacturer) for an animal drug who is submitting a product problem and/or an adverse event.
- A healthcare professional submitting a product problem and/or adverse event report involving a tobacco product
- A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving a tobacco product
- A clinical trial primary investigator or researcher who needs to report an adverse event involving c gene research study.
- A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.
- A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness or injury associated with dietary supplement(s), or a dietary supplement manufacturer, packer, or distributor who is submitting a voluntary adverse event and/or product problem report.
- None of these describe me.

### Your Contact Information

* First Name	<input type="text"/>
* Last Name	<input type="text"/>
* Primary Phone	<input type="text"/>
Other Phone	<input type="text"/>
Fax	<input type="text"/>
* Country	<input type="text" value="Please Select"/>
* Street Address Line 1	<input type="text"/>
Street Address Line 2	<input type="text"/>
* City/Town	<input type="text"/>
* State	<input type="text" value="Please Select"/>
State/Province	<input type="text"/>
* ZIP/Postal Code	<input type="text"/>

### Your Login Credentials

* Email Address (this will be your login ID)	<input type="text"/>
* Confirm Email Address	<input type="text"/>

Select a password:

- at least 8 characters long
- with no blank spaces
- at least one symbol/special character (Example: !, @, #, %, ^, &, \*, \_ , - , .)
- does not start or end with a number

* Password	<input type="text"/>
* Confirm Password	<input type="text"/>
* Security Question	<input type="text"/>
* Security Question Answer	<input type="text"/>

Submit

Exit

My Report History

My Account

## My Account

\* = Required

### Personal Information

#### Change Password and Security Question

\* Reporter Role

Representative of manufacturer/packer/distributor ( DSR) ▼

\* First Name

\* Last Name

\* Email Address (this will be your Login ID)

\* Confirm Email Address

\* Primary Phone

Other Phone

Fax

### Address Information

\* Country

United States ▼

\* Street Address 1

Street Address 2

\* City/Town

\* State

State/Province

\* Zip/Postal Code

Save

Exit

## New Guest Report

You have chosen to use the portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

**\*Select the option that best describes what you want to do:**

- Start a new report
- Follow-up on a report previously submitted as a guest portal user
- Follow-up on a report previously submitted as a logged in user.
- None of the above

## New Guest Report

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Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

**\*Select the option that best describes what you want to do:**

- Start a new report
- Follow-up on a report previously submitted as a guest portal user
- Follow-up on a report previously submitted as a logged in user.
- None of the above

**\*Which of the following best describes you?**

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- A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food.
- A veterinarian or veterinary staff member who is submitted a product problem and/or adverse event report involving pet food.
- A consumer or concerned citizen who is submitting a product problem and/or adverse event involving pet food.
- A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on a product problem and/or an adverse event.
- A healthcare professional submitting a product problem and/or adverse event report involving a tobacco product.
- A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving a tobacco product.
- A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.
- A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness or injury associated with dietary or a dietary supplement manufacturer, packer, or distributor who is submitting a voluntary adverse event and/or product problem report.
- A clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study.
- None of these describe me.

[Begin Report](#)

[Exit](#)

My Report History

My Account

Name: Mandatory Dietary Supplement Report

ID: 1234(I)

Created: 10/29/2012

OMB Approval Number: 0910-0645

OMB Expiration Date: 01/31/2013

### My Reports

#### Draft Reports

Click column header to sort the column

Date Saved (EST)	Report ID	Title	Type
<input checked="" type="radio"/> 10/10/2012 09:24:41 AM	3572 (I)	creatine	Mandatory Dietary Supplement Report
<input type="radio"/> 09/19/2012 08:45:33 AM	3012 (F)	Whey Supplement	Mandatory Dietary Supplement Report

|< < Page 1 of 1 > >|

#### Submitted Reports Available for Follow-Up

Submitted as of  (mm/dd/yyyy)

ICSR Number (please enter the number only) :

#### Submitted Reports

Click column header to sort the column

Date Submitted (EST)	Report ID	ICSR#	Title	Type
<input checked="" type="radio"/> 01/17/2012 05:39:41 PM	2245 (I)	1200716 (I)	Protein Treats	Mandatory Dietary Supplement Report
<input type="radio"/> 5/25/2012 09:45:33 AM	2500 (F)	1255245 (F)	Flaxseeds	Mandatory Dietary Supplement Report

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### Introduction

\* =Required

Introduction

Contact Information

Problem Summary

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Concomitant Products

Attachments

My Report History

OMB Approval Number: 0910-0645  
OMB Expiration Date: 01/31/2013

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). Manufacturers, packers, or distributors of dietary supplements whose names appear on the label of a dietary supplement marketed in the United States are required to submit to FDA on the MedWatch form (3500A) any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement. Serious adverse event reports received through the address or phone number on the label of a dietary supplement, as well as all follow-up reports of new medical information received by the responsible person within one year after the initial report, must be submitted to FDA no later than 15 business days after the report is received by the responsible person.

FDA has made available, for those who choose to use it, this method of electronic submission for mandatory serious adverse event reports about a dietary supplement. FDA will accept reports filed via this portal to satisfy firms' statutory reporting duty under section 761 of the FD&C Act and intends to exercise enforcement discretion for firms' failure to use the paper MedWatch form 3500A required by that section, provided that the responsible person has completed all required fields in and submitted this electronic form. Use of this electronic form (which contains some new mandatory questions) is completely voluntary and the paper MedWatch form 3500A will continue to be accepted until FDA conducts rulemaking to require use of an electronic form for mandatory reports. Instructions for completing the MedWatch 3500A form, on which this report is based, can be found here [link to: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm), and instructions specific to using the MedWatch 3500A form for mandatory dietary supplement serious adverse event reports can be found here [link to: http://www.fda.gov/Food/ComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171415.htm](http://www.fda.gov/Food/ComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171415.htm). Additionally, FDA has published industry guidance for submitting dietary supplement serious adverse event reports. This document can be found here [link to: http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm171383.htm](http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm171383.htm).

### Report Information

Please enter a title to help you identify this report.  
Consider using your firm's internal case tracking number for simplified recordkeeping.

\* What type of report are you submitting?

- Serious adverse event (a serious adverse health-related event associated with the product)
- Serious adverse event and product problem (e.g., defects that may have caused or contributed to a serious adverse event)

\* Enter the date you received the initial report:

How did the initial reporter learn of the serious adverse event or product problem?  
(check all that apply)

- Consumer
- Friend or Relative
- Distributor
- Health Professional
- Lawyer
- Social Media
- Other

If other, please describe

Save Draft Exit Submit Report

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**Introduction**

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FDA has made available, for those who choose to use it, this method of electronic submission for mandatory serious adverse event reports about a dietary supplement. FDA will accept reports filed via this portal to satisfy firms' statutory reporting duty under section 761 of the FD&C Act and intends to exercise enforcement discretion for firms' failure to use the paper MedWatch form 3500A required by that section, provided that the responsible person has completed all required fields in and submitted this electronic form. Use of this electronic form (which contains some new mandatory questions) is completely voluntary and the paper MedWatch form 3500A will continue to be accepted until FDA conducts rulemaking to require use of an electronic form for mandatory reports. Instructions for completing the MedWatch 3500A form, on which this report is based, can be found here [link to: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm), and instructions specific to using the MedWatch 3500A form for mandatory dietary supplement serious adverse event reports can be found here [link to: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171415.htm](http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171415.htm). Additionally, FDA has published industry guidance for submitting dietary supplement serious adverse event reports. This document can be found here [link to: http://www.fda.gov/food/guidancecompliance/regulatoryinformation/guidancedocuments/dietarysupplements/ucm171383.htm](http://www.fda.gov/food/guidancecompliance/regulatoryinformation/guidancedocuments/dietarysupplements/ucm171383.htm).

**Report Information**

Please enter a title to help you identify this report. Consider using your firm's internal case tracking number for simplified recordkeeping.

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- Serious adverse event (a serious adverse health-related event associated with the product)
- Serious adverse event and product problem (e.g., defects that may have caused or contributed to a serious adverse event)

\* Enter the date you received the initial report:

How did the initial reporter learn of the serious adverse event or product problem? (check all that apply)

- Consumer
- Friend or Relative
- Distributor
- Health Professional
- Lawyer
- Social Media
- Other

If other, please describe

Original ICSR number

Initial report date

\* Reason for follow-up

Save Draft Exit Submit Report

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Read-only fields pre-populated with the original SRP report submission information



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**Contact Information**  
\* = Required

**Manufacturer, Packer, or Distributor Site Information**

My account address is the same as the manufacturer, packer, or distributor address  Yes  No

\* Organization name

\* Organization type  
 Manufacturer  
 Packer  
 Distributor  
 Other

If other, please describe

Food facility registration number

\* Country

\* Street address 1

Street address 2

\* City/Town

State

State/Province

\* Mail/ZIP code

Postal code

This field is shown only for account holders and hidden for guests.

If "Yes", fields from "Country" through "Postal Code" will be populated and the rest of the fields are displayed empty and editable.  
If "No", all fields are displayed empty and editable.

For Guests:  
Show all fields from "Organization Name" through "Postal Code" empty and editable.

OTH Approval Number: 0410-0645  
OTH Expiration Date: 01/29/2013

**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

\* I am the point of contact for the facility listed above  Yes  No

First name

Last name

Job title

Email

Confirm email

Primary phone

Other phone

Fax

Only for guest reporters:

If the submitter is NOT the Site Point of Contact, then show "First Name" through "Fax" in this section, display Report Submitter Contact Information section with a full contact information block for the report submitter before the Initial Reporter.

If the submitter IS the Site Point of Contact, then populate "First Name" through "Fax" in this section, Report Submitter Contact Information section is hidden.

Only for account holders:

If the submitter is NOT the Site Point of Contact, then show "First Name" through "Fax" in this section as editable, Report Submitter Contact Information section is hidden.

If the submitter IS the Site Point of Contact, then populate "First Name" through "Fax" in this section, Report Submitter Contact Information section is hidden.

**Report Submitter Contact Information**

Please provide contact information for you, the person who is filing out this report

First name

Last name

Email

Confirm email

Phone

Fax

Country

Street address line 1

Street address line 2

City/Town

State

State/Province

Mail/Zip code

Postal code

**ALL HIGHLIGHTED ELEMENTS ARE "DRAFT"**

**Initial Reporter**

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 [link to: section 13 of the guidance.](#)

\* Did the initial reporter indicate that they also reported the event to the FDA?  Yes  No  Unknown

\* Does the initial reporter wish to remain anonymous to the FDA?  Yes  No

Salutation

First name

Last name

Email

Confirm email

Phone

Country

Street address line 1

Street address line 2

City/Town

State

State/Province

Mail/Zip code

Postal code

Was the initial reporter a healthcare professional?  Yes  No  Unknown

Healthcare professional type

If other, please describe

Save Draft Exit Submit Report

< Back Next >

link to: <http://www.fda.gov/food/guidance-compliance/regulatory-information/guidancedocuments/dietary-supplements/ucm171383.htm>

If yes, hide "Salutation" through "Postal code"

- Mr.
- Mrs.
- Ms.
- Miss.
- Dr.
- Rev.

- Physician
- Physician Assistant
- Nurse Practitioner
- Nurse
- Pharmacist
- Other

Welcome D. Manufacturer      Home    FAQs    Related Links    Contact Us    Feedback    Help

**Problem Summary**  
\* =Required

**Affected Individual Information**

\* Patient identifier

Gender  Female  Male

Age at time of event, if unknown, please enter  Select Unit of Measure ▾

Date of birth below

Date of birth

Weight  Select Unit of Measure ▾

**Height**    Select Unit of Measure ▾

**Adverse Event and/or Product Problem Description**

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

- Death
- A life-threatening experience
- Inpatient hospitalization
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Requires, based on a reasonable medical judgment, a medical or surgical intervention to prevent or outcome described above.
- Other serious (important medical events)

If other, please describe

Date of death:

\* Please describe the event or problem

Limit 2000 characters. If text exceeds 2000 characters, please attach additional documentation on the attachments tab.

Date of event

Duration of adverse event  Select Unit of Measure ▾

Please include a list of key terms from the adverse event or product problem narrative above. The terminology may be an accepted standard (e.g., MEDDRA), a verbatim term, or your own terminology.

Adverse Event Term(s)
Click on the Add button to add an item
<input type="button" value="Add"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/>

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Please provide relevant medical history, including pre-existing conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):

Do you have any relevant tests/laboratory data information to report?  Yes  No

**Relevant Tests/Laboratory Data**

Date of lab test	Lab test name	Test result(s)
Click on the Add button to add an item		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

blue text = conditional field

Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different) to locate the case if contacted for follow-up. Do not use the patient's name or social security number.

**HIGHLIGHTED ELEMENTS ARE "DRAFT"**

Adverse Event Term(s)
<input type="radio"/> Hepatitis B virus
<input type="button" value="Add"/> <input type="button" value="Edit"/>

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Date of lab test	Lab test name	Test result(s)
<input type="radio"/> 10/12/2012	CBC	high WBC
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	

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**Adverse Event Terms**

Please start typing the term name in the "Adverse event term" box. The form will display all of the terms with that name in the drop down menu below. If your term is not displayed, please choose "other."

\* Adverse event term

Type to search and select

If other, please describe

Save Cancel

blue text = conditional field

Type ahead control with "Other" option always available

- al
- alve
- allerest
- valium
- 
- Other

Type ahead will find partial string matches. For example, when a user types "ai" words that start with ai as well as words that contain ai, will be provided in the list of matches.

Relevant Tests/Lab Data

Lab test name

If other, please describe

Date of lab test

 

Test result(s)

 

blue text = conditional field

blue text = conditional field

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OMB Approval Number: 0910-0645  
 OMB Expiration Date: 01/31/2013

### Suspect Product(s)

\* =Required

#### \* Suspect Product Details

For adverse event reporting, a suspect product is one that the initial reporter suspected was associated with the adverse event. 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. Product labels can be attached on the Attachments tab.

Name	Manufacturer/distributor/packer	Strength	UOM
Click on the Add button to add an item			
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>	< < Page 1 of 1 > >

FDA recognizes the burden that completely filling out the following section may present. Please note that this sub-section is optional, and we appreciate any effort you can make to provide ingredient information.

#### Ingredient details for <suspect product name>

Ingredient Name	Amount	UOM
Click on the Add button to add an item		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

\* I have reviewed the ingredients listed for each product, if available, and made any necessary corrections

Only asked if one or more products has ingredients listed; otherwise hidden

#### Grid view after products are added

Name	Manufacturer/distributor/packer	Strength	UOM
<input type="radio"/> Joint-Ease	ABC	150	mg
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>	< < Page 1 of 1 > >

#### Grid view with ingredients linked to the product (pre-filled based on the product selected)

Ingredient Name	Amount	UOM
<input type="radio"/> Ibuprofen	300	mg
<input type="radio"/> Vitamin D	200	g
<input type="radio"/> Calcium	45	mg
<input type="radio"/> Vitamin B12	10	ug
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	< < Page 1 of 1 > >

Suspect Product Details

Blue text = conditionally field

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

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

Type to search and select

Auto-complete list based on CFSAN supplied list of standard products

al

aleve  
allerest  
valium

Partial matches at the beginning and within terms are included

If other, please provide full product name:

Product manufacturer, packer, or distributor

Product strength

Select Unit of Measure

Barcode identifier

Identifier type

UPC  
Other

If other, please describe

\* Diagnosis or reason for use (indication):

Text input field for diagnosis or reason for use.

Limit 2000 characters. If text exceeds 2000 characters, please attach additional documentation on the attachments tab.

Lot number

Text input field for lot number.

Expiration/use-by date

Date input field for expiration/use-by date.

Please choose the last day of the calendar month if no day is specified on the product

How Product Was Used

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

Start / / End / /

Duration of product use

Text input field for duration of product use.

Frequency of consumption

Text input field for frequency of consumption.

Amount consumed per serving

Text input field for amount consumed per serving.

Administration route

Please select dropdown menu for administration route.

Did the event stop when product use stopped or the amount consumed was reduced?

Radio buttons: Yes, No, Unknown, Not Applicable

Did the event reoccur when product use resumed?

Radio buttons: Yes, No, Unknown, Not Applicable

Please provide any notes describing the product's usage:

Text input field for notes describing the product's usage.

ABC

Save Cancel

## Add Ingredient

**Ingredient details for <suspect product name>**

Please start typing the ingredient name in the "Ingredient name" box. The form will display all of the ingredients with that name in the drop down box menu below. If the ingredient is not displayed, please choose "other".

Ingredient name

*If other, please describe*

Ingredient amount

Blue text = conditionally field

Auto-complete control with "Other" option always available

al

aleve

allerest

valium

-----

Other

Auto-complete list based on CFSAN supplied list of standard ingredients

Partial matches at the beginning and within terms are included

## Edit Ingredient

**Ingredient details for <suspect product name>**

Ingredient name

Ingredient amount

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**Concomitant Product(s)**  
 \* =Required

**Concomitant Product Details**

For adverse event reporting, a suspect product is one that the initial reporter suspected was associated with the adverse event. Concomitant products are other products that include either dietary supplements, drugs, or devices that the affected individual was using at the time of the event but that are NOT thought by the initial reporter to be involved in the event.

Name	Manufacturer/distributor/packer	Strength	UOM
Click on the Add button to add an item			
<input type="button" value="Add"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/> <span style="float: right;"> &lt; &lt; Page 1 of 1 &gt; &gt; </span>			

FDA recognizes the burden that completely filling out the following section may present. Please note that this sub-section is optional, and we appreciate any effort you can make to provide ingredient information.

**Ingredient details for <concomitant product name>**

Ingredient Name	Amount	UOM
Click on the Add button to add an item		
<input type="button" value="Add"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/>		

\* I have reviewed the ingredients listed for each product, if available, and made any necessary corrections

blue text = conditional field

Name	Manufacturer/distributor/packer	Strength	UOM
<input type="radio"/> Joint-Ease	ABC	150	mg
<input type="button" value="Add"/> <input type="button" value="Edit"/> <input type="button" value="Delete"/> <span style="float: right;"> &lt; &lt; Page 1 of 1 &gt; &gt; </span>			

Ingredient Name	Amount	UOM
<input type="radio"/> Ibuprofen	300	mg
<input type="button" value="Add"/> <input type="button" value="Edit"/> <span style="float: right;"> &lt; &lt; Page 1 of 1 &gt; &gt; </span>		

Only asked if one or more products has ingredients listed, otherwise



**Concomitant Product Details**

blue text = conditional field

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

Full name of product as it appears on the package label

al
aleve
allerest
valium
-----
Other

Auto-complete list based on CFSAN supplied list of standard products

Partial matches at the beginning and within terms are included

*If other, please describe*

Product manufacturer, packer, distributor or other responsible party

Product strength

Select Unit of Measure ▼

Barcode identifier

Identifier type ▼

UPC
Other

*If other, please describe*

Diagnosis or reason for use (indication):

**ABC** Limit 2000 characters. If text exceeds 2000 characters, please attach additional documentation on the attachments tab.

Lot number

Expiration/use-by date <sup>?</sup>

Please choose the last day of the calendar month if no day is specified on the product

**How Concomitant Product Was Used**

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

Start   End

Duration of product use

Please select ▼

Frequency of consumption/use

Select Unit of Measure ▼

Amount consumed per serving

Select Unit of Measure ▼

Administration route

Please select ▼

Please provide any notes describing the product's usage:

**ABC**

Save Cancel

**Ingredient details for <concomitant product name>**

Please start typing the ingredient name in the "Ingredient Name" box. The form will display all of the ingredients with that name in the drop down menu below. If your ingredient is not displayed, please choose "other."

Ingredient name

*If other, please describe*

Ingredient amount

blue text = conditional field

Auto-complete control with "Other" option always available

al

aleve

allerest

valium

-----

Other

Auto-complete list based on CFSAN supplied list of standard ingredients

Partial matches at the beginning and within terms are included

- Introduction
- Contact Information
- Problem Summary
- Products
- Concomitant Products

**Attachments**  
 \* =Required  
 You may upload up to 5 (10 MB each) attachments per submission. The following file extensions are permitted:  
 .doc, .docx, .pdf, .bmp, .gif, .jpg, .jpeg, .png, .tif, .tiff, .txt, .rtf, .xls, .xlsx, .wpd.

Attachments

**My Report History**

OMB Approval Number: 0910-0645

OMB Expiration Date: 01/31/2013

File to attach	Type of Attachment	Description of Attachment
<input type="radio"/> Lab Results	Multiple results	Lab results for affected person
<input type="radio"/> Product label	photograph	Picture of product label

|< <Page 1 of 1 > >|

**Attach File**

\*File to attach

\*Description of Attachment

\*Type of Attachment  ▼

**Attach File**



- Introduction
- Contact Information
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- Products
- Concomitant Products
- Attachments
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## Report Submission Confirmation

**X** Sorry, but you have not completed all of the required questions in this report. You can use the left navigation menu or click on the first item in the list below:

[Introduction](#)

[Contact Information](#)

[Problem Summary](#)

[Products](#)

- Introduction
- Contact Information
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- Concomitant Products
- Attachments
- My Report History

### Report Submission Confirmation

Congratulations! Your initial Mandatory Dietary Supplement Serious Adverse Event Report, ID 3811, was successfully submitted on 10/1/2012 12:08:14 PM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 1201886. Thank you for using the Safety Reporting Portal.

[View Report](#)

[View Report PDF](#)

[Return to My Report History](#)

This will be "Your follow-up Mandatory Dietary Supplement Serious Adverse Event Report." when a follow-up is submitted