

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 a 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
- at least one symbol/special character (Example: !, @, #, %, ^, &, *, _ , - , .)
- with no blank spaces
- 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

A concerned citizen/healthcare professional (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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***Select the option that best describes what you want to do:**

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

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- A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on a product problem and/or an adverse event.
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- None of these describe me.

[Begin Report](#)

[Exit](#)

My Report History

My Account

Name: Voluntary 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	Voluntary Dietary Supplement Report
<input type="radio"/> 09/19/2012 08:45:33 AM	3012 (F)	Whey Supplement	Voluntary Dietary Supplement Report

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Submitted Reports Available for Follow-Up

Submitted as of

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	Voluntary Dietary Supplement Report
<input type="radio"/> 5/25/2012 09:45:33 AM	2500 (F)	1255245 (F)	Flaxseeds	Voluntary Dietary Supplement Report

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Introduction

* =Required

You have chosen to use this electronic portal to submit a voluntary report to FDA about an adverse event associated with a dietary supplement (an adverse health-related event, such as an illness or injury) and/or a product problem with a dietary supplement.

Please be advised that under 18 U.S.C. 1001, anyone making a materially false, fictitious or fraudulent statement to the U.S. Government is subject to criminal penalties.

This report has up to 5 sections. After you answer the questions on this page, you may complete the other pages in any order. The amount of time required to complete this report will vary depending on the information you have to provide. As you complete each page, your responses are automatically saved. To submit this report, you must complete all required fields that are marked with a red asterisk.

Instructions for completing the MedWatch 3500 form, on which this report is based, can be found here [link to: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149236.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149236.htm).

Report Information

Please enter a title to help you identify this report

* What type of report are you submitting?

- Adverse event (an adverse health-related event associated with the product)
- Product problem (e.g., defects that may have caused or contributed to an adverse event)
- Both

Original ICSR number

Initial report date

* Reason for follow-up

Read-only fields pre-populated with data about the original SRP submission

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*
=Required

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Contact Information

* =Required

Your Contact Information

Do you wish to remain anonymous to the FDA?

Yes

No



If yes, hide "First Name" through "Postal code"

First name

Last name

Email

Confirm email

Phone

Country

Please select ▼

Street address line 1

Street address line 2

City/Town

State

Please select ▼

State/Province

Mail/Zip code

Postal code

Have you reported the event to any of the following? :

- Manufacturer
- Distributor
- Packer

Are you a healthcare professional?

Yes

No

Healthcare professional type

Please select ▼

If other, please describe

Save Draft

Exit

Submit Report

< Back

Next >

Physician
 Physician Assistant
 Nurse Practitioner
 Nurse
 Pharmacist
 Other

blue text = conditional field

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Problem Summary

*=Required

Affected Individual Information

* Patient identifier

Gender Female Male

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

Date of birth

Weight Select Unit of Measure

Height Select Unit of Measure

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.

Adverse Event and/or 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 an outcome described above.
 - Other

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 list key symptoms or injuries from your narrative above:

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"/>

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"/>		

HIGHLIGHTED AREAS 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" 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

 

Result

blue text = conditional field

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Introduction **Suspect Product(s)**

Contact Information *Required

Problem Summary For adverse event reporting, a suspect product is one that you, the reporter, suspect was associated with the adverse event.

Products *** Suspect Product Details**

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

blue text = conditional field

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 > >

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

Suspect Product Details

blue text = conditional field

For adverse event reporting, a suspect product is one that you suspect was associated with the adverse event. Please start typing the brand or name of the product in the "Suspect product name" box. 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".

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

If other, please provide full name of product

Product manufacturer, packer, distributor

Product strength

Barcode identifier

If other, please describe

Auto-complete list based on CFSAN supplied list of standard products
Partial matches at the beginning and within terms are included

- al
- aleve
- allerest
- valium
-
- Other

UPC
Other

* Diagnosis or reason for use (indication):

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

Lot number

Expiration/use-by date

Is the product available for evaluation by FDA? Yes No Unknown

Was product returned to manufacturer? Yes No Unknown

Date product was returned to manufacturer

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

Frequency of consumption

Amount consumed per serving

Administration route

Did the event stop when product use stopped or the amount consumed was reduced? Yes No Unknown Not Applicable

Did the event reoccur when product use resumed? Yes No Unknown Not Applicable

Please provide any notes describing the product's usage:

APC

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 Select Unit of Measure

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

blue text = conditional field

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Other Concomitant Product(s)

* =Required

Other Concomitant Product Details

For adverse event reporting, a suspect product is one that you suspect was associated with the adverse event. Other concomitant products include other dietary supplements, drugs, or devices that the affected individual was using at the time of the event but that are not thought by you, the 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"/>	< < 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 <other 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

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 > >

Ingredient Name	Amount	UOM
<input type="radio"/> Ibuprofen	300	mg
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	< < Page 1 of 1 > >

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

Other Concomitant Product Details

blue text = conditional field

Please start typing the brand or name of the product in the "Full name of other concomitant 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 box menu below. If your product is not displayed, please choose "other".

Full name of other concomitant product as it appears on the package label

Type to search and select

If other, please describe

Product manufacturer, packer, distributor or other responsible party

Product strength

Select unit of measure

Barcode identifier

Identifier type

If other, please describe

Diagnosis or reason for use (indication):

[Large text area for diagnosis]

ABC

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

Lot number

Expiration/use-by date

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

- al
- aleve
- allertest
- valium
-
- Other

Auto-complete list based on CFSAN supplied list of standard products
Partial matches at the beginning and within terms are included

- UPC
- Other

How Other 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

Select unit of measure

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:

[Large text area for usage notes]

ABC

Save Cancel

blue text = conditional field

Ingredient details for <other 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 **Select Unit of Measure**

Auto-complete control with "Other" option always available

al
alve
allerest
valium

Other

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

Partial matches at the beginning and within terms are included

ALL HIGHLIGHTED ELEMENTS ARE "DRAFT"

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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.

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

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Attach File

*File to attach

*Description of Attachment

*Type of Attachment

Attach File



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Report Submission Confirmation



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:

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Report Submission Confirmation

Congratulations! Your initial Voluntary Dietary Supplement 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.

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[View Report PDF](#)

[Return to My Report History](#)

This will be "Your follow-up Voluntary Dietary Supplement Report." when a follow-up is submitted