

## 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

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

[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

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.
- None of these describe me.

### Your Contact Information

*First Name	<input type="text"/>
*Last Name	<input type="text"/>
Job Title	<input type="text"/>
* Organization 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 yur login ID)	<input type="text"/>
*Confirm Email Address	<input type="text"/>
<div style="border: 1px solid black; padding: 5px; background-color: #e0f2f1;"> <p>Select a password:</p> <ul style="list-style-type: none"> <li>· at least 8 characters long</li> <li>· with no blank spaces</li> <li>· at least one symbol/special character (Example: !, @, #, %, ^, &amp;, *, _ , - , .)</li> <li>· does not start or end with a number</li> </ul> </div>	
*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- Drug Manufacturer

Change Password and Security Question

\* Reporter Role

Representative of a manufacturer for an animal drug (FdaGL42) ▼

Read only

\* First Name

\* Last Name

Job Title

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

\* Confirm Email Address

\* Primary Phone

Other Phone

Fax

## Address Information - Drug Manufacturer

Organization Name

\* Country

United States ▼

\* Street Address 1

Street Address 2

\* City/Town

State

1) State/Province

\* Zip/Postal Code 1

Save

Exit

1) Show if country <> US

1) If a ZIP/Postal Code is not applicable to your address, please type "NA" in the field.

My Report History

My Account

**My Reports****Draft Reports**    Click column header to sort the column

Date Saved (EST)	Report ID	Title	Type
<input checked="" type="radio"/> 09/27/2012 09:24:41 AM	3572 (I)	usa-medpharm	Mandatory Animal Drug Report
<input type="radio"/> 09/19/2012 08:45:33 AM	3012 (F)	usa-medpharm1	Mandatory Animal Drug Report

|&lt; &lt; Page 1 of 1 &gt; &gt;|

**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)	trial results	Mandatory Animal Drug Report
<input type="radio"/> 5/25/2012 09:45:33 AM	2500 (F)	1255245 (F)	med-0002	Mandatory Animal Drug Report

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### Introduction

\* =Required

You have chosen to submit an Animal Drug Safety Report to the FDA. Please be advised that under 18 U.S.C. 1001, anyone who makes 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 upon the information you have to provide. As you complete each field, your responses are automatically saved. To submit this report, you must complete all required fields that are marked with a red asterisk.

#### Report Identifying Information

Enter a title to help you identify this report

\*Original Receive Date  /

Please note, you must answer the following questions before you can advance to another section of the report

\* What type of report are you submitting?

Adverse Event ( a symptom, reaction, or disease associated with the product)  
 Product Problem (an observed or detected product or defect that has the potential to cause harm)  
 Both

\* Type of submission 1

\* Reason for nullification

Type of information in report 2

\* Report identifier (application number) 3

\* Country where adverse event occurred

\* Marketing Authorization Holder (MAH) Identifier 4

\* Unique case number 5

\* Unique adverse event report identification number 6

#### Report numbers of linked reports

Unique AER identification number	Explanation for linkage
Click on the Add button to add a report number	
<input type="button" value="Add"/>	<input type="button" value="Edit"/>
<input type="button" value="Delete"/>	

\* Domestic vs. Foreign Report Category 7

Domestic  
 Foreign -Same  
 Foreign-Similar  
 Other

\* Office of Regulatory Affairs, District Field Office 8

Original ICSR Number

\* Initial Report Date

1)Refer to the Guidance for Industry #188, section A.4.4.1  
 2)Refer to the Guidance for Industry #188, section A.4.4.3  
 3)Refer to the Guidance for Industry #188, section B.7.1  
 4))Refer to the Guidance for Industry #188, section A.1 (RA) or section A.2 (MAH)  
 5)Refer to the Guidance for Industry #188, section A.4.1  
 6)Refer to the Guidance for Industry #188, section A.1  
 7))Refer to the Guidance for Industry #188, section B.2.1.2 and B.7.2  
 8)Refer to the Guidance for Industry #188, section B.2.6.5

Unique AER identification number	Explanation for linkage
<input type="radio"/> 1254452	Duplicate report
<input type="radio"/> 1254456	Parent offspring
<input type="button" value="Add"/>	<input type="button" value="Edit"/>

**Unique AER identification number for linked reports**

Unique AER identification number for linked report

\*Explanation for Linkage

- Parent offspring
- Same patient
- Similar reports from same reporter (cluster)
- Duplicate report
- Other link type

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Contact Information

\* =Required

Marketing Authorization Holder (MAH)

\* Business Name

\* Country

\* Street Address Line 1

\* City/Town

\* State

State/Province

\* Mail/Zip Code

Person Acting on Behalf of MAH

First name

Last name

Title

Email

Confirm email

Phone

Fax

Pharmacovigilance Contact Person

Is the Person Acting on Behalf of MAH also the Pharmacovigilance Contact Person?  Yes  No  Unknown

Business Name

\* First name

\* Last name

Title

\* Email

\* Confirm email

\* Phone

Fax

Regulatory Authority (RA)

\* Regulatory Authority Name

\* Country

\* Street Address Line 1

\* City/Town

\* State

\* Mail/Zip Code

Primary Reporter

\* Reporter Category  Veterinarian  Animal Owner  Physician  Patient  Other Health Care Professional  Unknown  Other

\* Does this reporter wish to remain anonymous?  Yes  No

First Name

\* Last Name

Email

Confirm email

Phone

Fax

Business Name

\* Country

Street Address Line 1

City/Town

State

State/Province

Mail/Zip Code

Is there another reporting source?  Yes  No

Other Reporter

\* Reporter Category  Veterinarian  Animal Owner  Physician  Patient  Other Health Care Professional  Unknown  Other

\* Does this reporter wish to remain anonymous?  Yes  No

First Name

Last Name

Email

Confirm email

Phone

Fax

Business name

Country

Street Address Line 1

City/Town

State

State/Province

Mail/Zip Code

Save Draft Exit Submit Report

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1) Refer to the Guidance for Industry #188, section A.1



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**Problem Summary**

\* =Required

**Animal Information**

Number of Animals Treated <sup>1</sup>

\*Number of Animals Affected

\*Species <sup>2</sup>

Are there any purebred animals?  Yes  No  Unknown

**Purebred Animals**

Click on the Add button to add a breed

<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>	< <Page 1 of 1 > >
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Are there any crossbred animals?  Yes  No  Unknown

**Crossbred Animals**

Click on the Add button to add a breed

<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>	< <Page 1 of 1 > >
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Gender

Reproductive Status <sup>3</sup>

Female Physiological Status

\*Is age of affected animal(s)  Measured  Estimated  Unknown

\*Minimum Age

Maximum Age

\*Is weight of affected animal(s)  Measured  Estimated  Unknown

\*Minimum Weight

Maximum Weight

Attending Veterinarian's Assessment of Animal Health Status Prior to Administering the Product

Excellent  Good  Fair  Poor  Critical  Unknown  No Attending Veterinarian

**Problem Description**

\* Narrative of Adverse Event/Product Problem

\* Date of Onset of Adverse Event/Product Problem (Adverse Event start date/Product Problem found date)

Duration of Adverse Event

Length of time between exposure to Product and Onset of Adverse Event

Were the symptoms treated?  Yes  No  Unknown

\*Was the adverse event serious?  Yes  No

\*Adverse Clinical Manifestations

VeDDRA Terms	Number of Animals	Accuracy
Click on the Add button to add a term		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		

FDA Product Problem Terms	Number of Animals	Accuracy
Click on the Add button to add a term		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		

FDA Adverse Event Terms	Number of Animals	Accuracy
Click on the Add button to add a term		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		

**Outcomes to Date (Number of Animals)**

For the following fields, all values must be numeric. Text and symbols cannot be entered.

Number experiencing ongoing symptoms

Number recovered/normal

Number recovered with sequela

Number died

Number euthanized

Number with unknown outcome

1)Animals Treated means animals exposed to the VMP, does not have to be intentional exposure, as this may happen accidentally.  
 2)The class or kind of animal that is the subject of the adverse event; e.g., horse or cow.  
 3)Intact means not spayed or neutered.  
 4) Refer to the Guidance for Industry #188, section B.3.2

**Purebred Animals**

Landrace- German  Pietrain

<input type="button" value="Add"/>	<input type="button" value="Edit"/>	< <Page 1 of 1 > >
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**Crossbred Animals**

Retriever- Golden  Hound (unspecified)

<input type="button" value="Add"/>	<input type="button" value="Edit"/>	< <Page 1 of 1 > >
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VeDDRA Terms	Number of Animals	Accuracy
<input type="radio"/> Chronic Renal Failure	2	Estimated
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		

FDA Product Problem Terms	Number of Animals	Accuracy
<input type="radio"/> Tablets, Abnormal	1	Actual
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		

FDA Adverse Event Terms	Number of Animals	Accuracy
<input type="radio"/> INEFFECTIVE, HEARTWORM ADULTS	3	Actual
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>
< <Page 1 of 1 > >		



**Breed Components**

\*Breed

### Adverse Clinical Manifestations- VeDDRA Terms

\*VeDDRA Term

Please select

Number of Animals Associated  
with Each Clinical Manifestation

Accuracy of the Number of Animals

Please select

Save

Cancel

### Adverse Clinical Manifestations- FDA Product Problem Terms

\*FDA PP Term

Please select

Number of Animals Associated  
with Each Clinical Manifestation

Accuracy of the Number of Animals

Please select

Save

Cancel

### Adverse Clinical Manifestations- FDA Adverse Event Terms

\*FDA AE Term

Please select

Number of Animals Associated  
with Each Clinical Manifestation

Accuracy of the Number of Animals

Please select

Save

Cancel

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### Products

\* =Required

#### Event and Product Relatedness

- Did the adverse event abate after stopping the VMP(s)?  Yes  No  Unknown  Not Applicable
- Did the adverse event reappear after reintroducing the VMP(s) ?  Yes  No  Unknown  Not Applicable
- Attending Veterinarian's assessment of the association between the VMP(s) and the adverse event
- Probable
  - Possible
  - Unlikely
  - Unknown
  - No Assessment
  - No Attending Veterinarian

#### Product Details

\*Product Details

Product Name	Marketing Authorization Holder	Registration ID
Click on the Add button to add an item		
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>

At least one MAH product must be reported.

#### Regulatory Authority Assessment Term

Regulatory Authority Assessment Term	Explanation
Click on the Add button to add an item	
<a href="#">Add</a>	<a href="#">Edit</a>

\*Ingredient detail for <product name>

Active Ingredient Name	AI Code	Strength (numerator)	UOM	Strength
Click on the Add button to add an item				
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>		

Dosing schedule for <product name>

Dose	UOM	Route	First Exposure	Last Exposure
Click on the Add button to add an item				
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>		

Product lots for <product name>

Lot#	Exp. Date	Manuf.SiteID/Type	Manuf. Date	No defective items	No returned items
Click on the Add button to add an item					
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>			

[Save Draft](#) [Exit](#) [Submit Report](#)

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\*Product Details

Product Name	Marketing Authorization Holder	Registration ID
<input checked="" type="radio"/> Flex-Joint	usa-Pharm	USA-gooddrug-Z778556
<input type="radio"/> joint relief	UAT	USA-badddrugs-N445856
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>

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#### Regulatory Authority Assessment Term

Regulatory Authority Assessment Term	Explanation
<input type="radio"/> Probable	Highly likely VMP caused the AE
<a href="#">Add</a>	<a href="#">Edit</a>

Ingredient detail for Flex-Joint

Active Ingredient Name	Code	Strength (numerator)	UOM	Strength (denominator)	UOM
<input type="radio"/> glucosamine	glc	5	Milligram	1	liter
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>			

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Dosing schedule for Flex-Joint

Dose	UOM	Route	First Exposure	Last Exposure
<input type="radio"/> 1	capsule	ORAL	9/5/2012	9/12/2012
<a href="#">Add</a>	<a href="#">Edit</a>	<a href="#">Delete</a>		

|< <Page 1 of 1 > >|

Product lots for Flex-Joint

Lot#	Exp. Date	Manuf.SiteID/Type	Manuf. Date	No. defective items	No. returned items
<input type="radio"/> 457	10/31/2014	1234564 DUNS	10/31/2012	251	250
<a href="#">Add</a>	<a href="#">Edit</a>				

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**Product Details**

\*Registered or Brand Name

BC

\* Do you represent the party responsible for pharmacovigilance?  Yes  No

Company or MAH

BC

\*Country Where Drug was Approved

\*Regulatory Authority Identifier

\*Registration Number

\*Registration Identifier

Product Code

MAH assessment of the association between the VMP(s) and the adverse event

BC

Was the animal(s) exposed to this product(s) previously?  Yes  No  Unknown  Not Applicable

Were adverse clinical signs observed with the previous use of this product(s)?  Ye  No  Unknown

\* Anatomical Therapeutic Chemical Vet (ATCVet) Code

Dosage Form

Was the product used according to label directions?  Yes  No  Unknown

Explanation for Off-Label Use:

Was the target species off-label?

Was the route of administration off-label?

Was the animal overdosed?

Was the animal underdosed?

Was the treatment regimen off-label?

Was the indication off-label?

Was the storage condition off-label?

Was the product expired?

Was there any other off-label issue?

Who administered the VMP?

- Veterinarian
- Animal Owner
- Physician
- Patient
- Other Health Care Professional
- Multiple Administrators
- Other
- Unknown

Save Cancel

1)Refer to the Guidance for Industry #188, section A.1  
2))Refer to the Guidance for Industry #188, section B.2.1.2  
3))Refer to the Guidance for Industry #188, section B.2.1.1  
4)Refer to the Guidance for Industry #188, section B.2.1.3

## Regulatory Authority Assessment Term

Regulatory Authority Assessment Term

Please select

Explanation Relating to Assessment

Save

Cancel

**Ingredient detail for <product name>**

\* Active Ingredient Name

Active Ingredient Code  ✓ ABC

\* Numeric Value for Strength (numerator)  Select Unit of Measure ▼

\* Numeric Value for Strength (denominator)  Select Unit of Measure ▼

1

2

1) Refer to the Guidance for Industry #188, section B.2.2.1.2  
2) Refer to the Guidance for Industry #188, section B.2.2.1.1

### Dosing Schedule for <product name>

Numeric Value for Dose (Numerator)

Select Unit of Measure ▼

Numeric Value for Dose (Denominator)

Select Unit of Measure ▼

Numeric value for Interval of Administration

Select Unit of Measure ▼

Route of Exposure

 ▼

Date of First Administration (Exposure)



Date of Last Administration (Exposure)




Save

Cancel

Product Lots for <product name>

Lot Number ? 1


Expiration Date

Manufacturing Site Identifier Number  
(FDA Establishment Identifier Number)

Product Manufacture Date

Number of Defective Items

Number of Items Returned

1) Lot number is typically a string of numbers located near the expiration/use-by date.



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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 Name	Type	Description
<input type="radio"/> Lab Results	Multiple results	Lab results for affected animals
<input type="radio"/> Clinical notes	Record	Notes on affected animals

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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 screens 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 Mandatory Animal Drug 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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**JBS International, Inc.**

5515 Security Lane, Suite 800  
North Bethesda, MD 20852

