Safety Reporting Portal

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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.

Begin Reporting Here

1. Login

Email

Password

Forgot your password?

Remember me

Login

Or

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

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

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	
*Last Name	
Job Title	
* Organization Name	
* Primary Phone	
Other Phone	
Fax	
* Country	Please Select
* Street Address Line 1	
Street Address Line 2	
* City/Town	
* State	Please Select
State/Province	
*ZIP/Postal Code	

Your Login Credentials

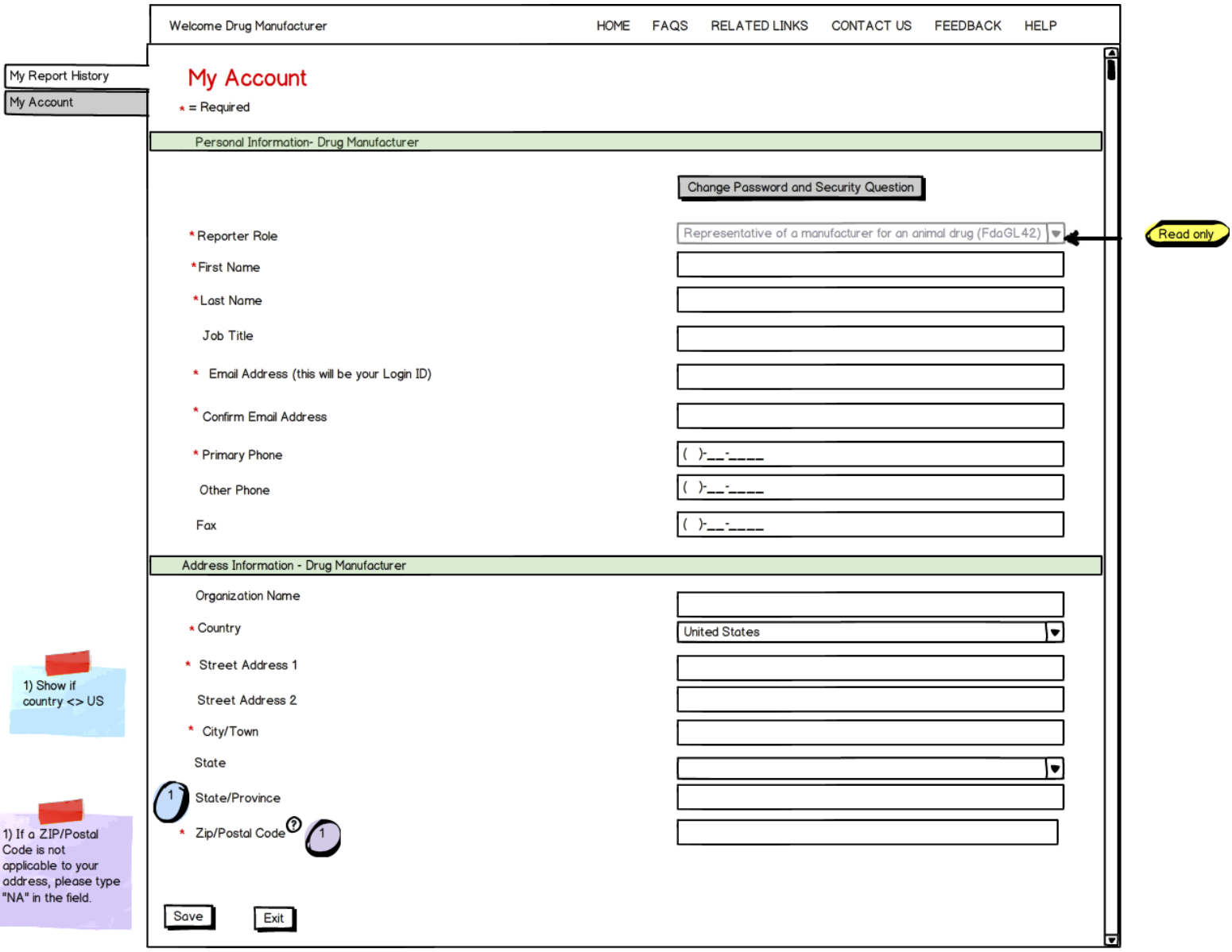
*Email Address (this will be yur login ID)	
*Confirm Email Address	

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	
*Confirm Password	
*Security Question	
*Security Question Answer	

Submit Exit


Welcome Drug Manufacturer
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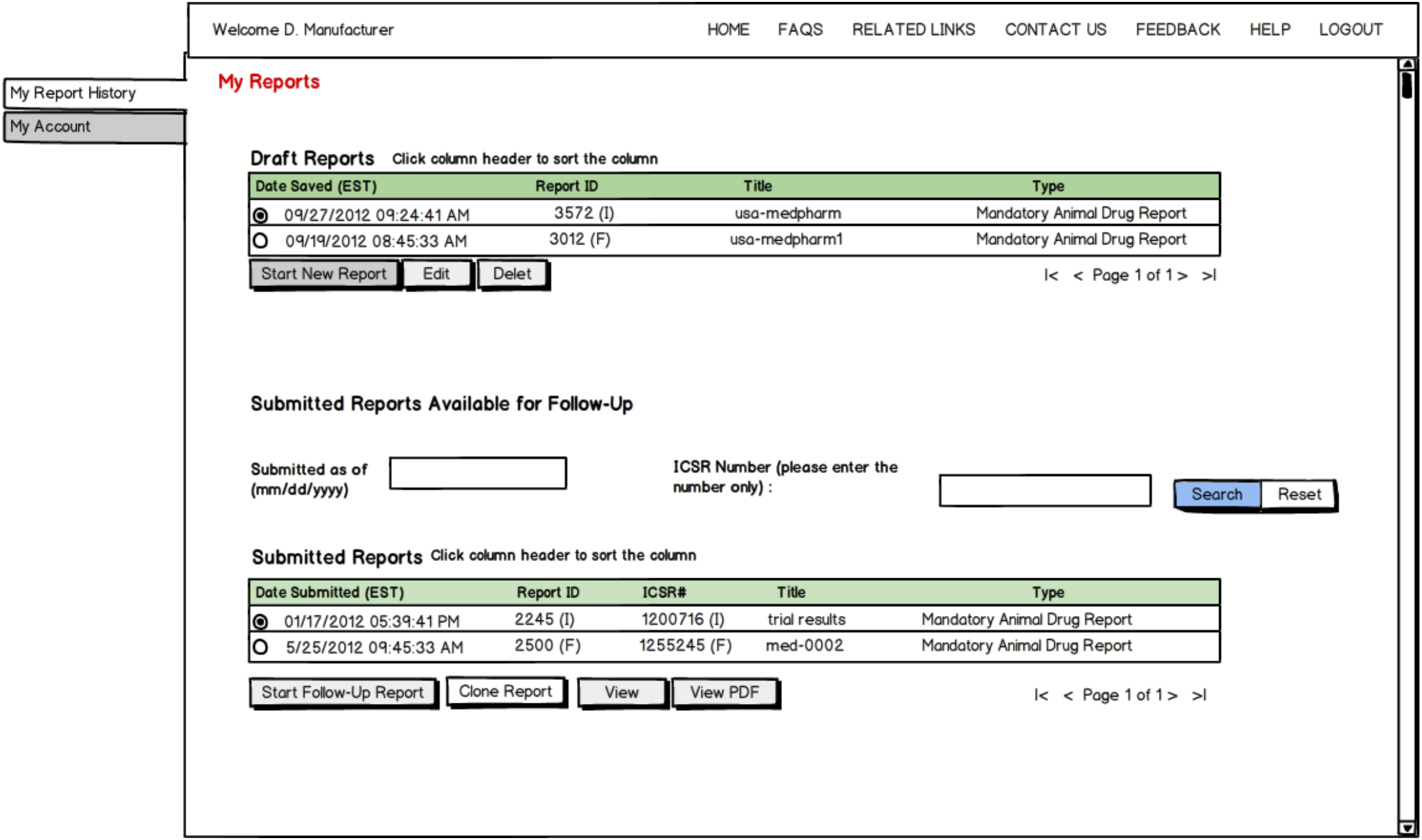
* = Required
Personal Information- Drug Manufacturer
Change Password and Security Question
*Reporter Role
Representative of a manufacturer for an animal drug (FdaGL42)
Read only
*First Name
*Last Name
Job Title
* Email Address (this will be your Login ID)
* Confirm Email Address
* Primary Phone
( )-__-____
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.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Draft Reports
Click column header to sort the column
Date Saved (EST)
Report ID
Title
Type
09/27/2012 09:24:41 AM
3572 (I)
usa-medpharm
Mandatory Animal Drug Report
09/19/2012 08:45:33 AM
3012 (F)
usa-medpharm1
Mandatory Animal Drug Report
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Submitted Reports Available for Follow-Up
Submitted as of (mm/dd/yyyy)
ICSR Number (please enter the number only) :
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ICSR#
Title
Type
01/17/2012 05:39:41 PM
2245 (I)
1200716 (I)
trial results
Mandatory Animal Drug Report
5/25/2012 09:45:33 AM
2500 (F)
1255245 (F)
med-0002
Mandatory Animal Drug Report
Start Follow-Up Report
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View PDF
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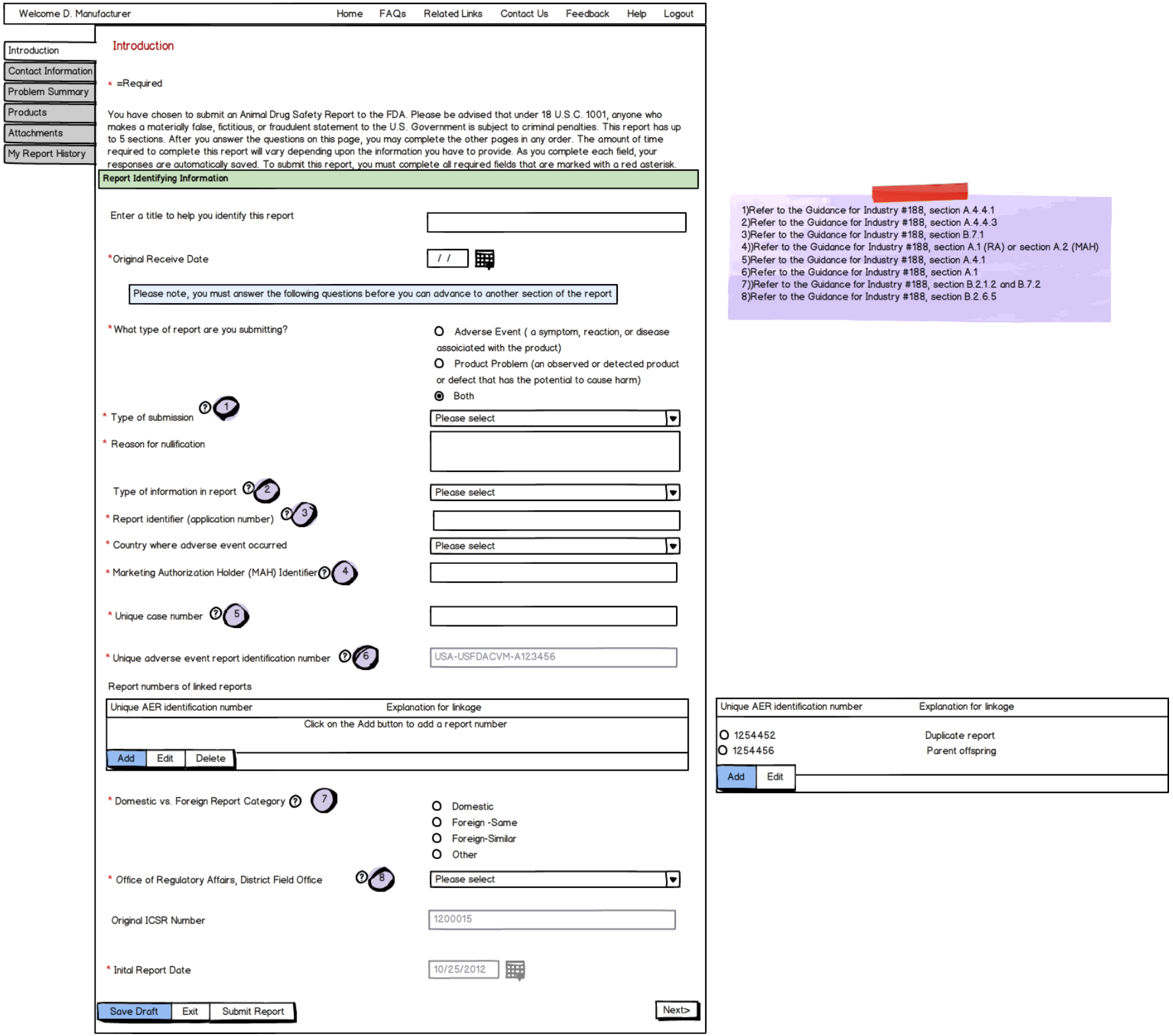
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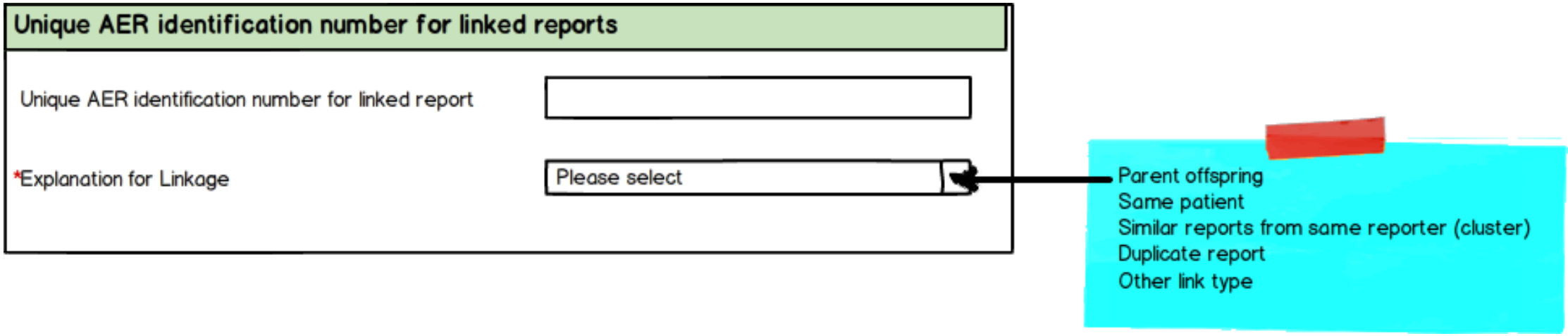
Introduction
* =Required
You have chosen to submit an Animal Drug Safety Report to the FDA. Please be advised that under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. This report has up to 5 sections. 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 assoiciated with the product)
Product Problem (an observed or detected product or defect that has the potential to cause harm)
Both
* Type of submission
1
Please select
* Reason for nullification
Type of information in report
2
Please select
* Report identifier (application number)
3
* Country where adverse event occurred
Please select
* Marketing Authorization Holder (MAH) Identifier
4
* Unique case number
5
* Unique adverse event report identification number
6
USA-USFDACVM-A123456
Report numbers of linked reports
Unique AER identification number
Explanation for linkage
Click on the Add button to add a report number
Add
Edit
Delete
* Domestic vs. Foreign Report Category
7
Domestic
Foreign -Same
Foreign-Similar
Other
* Office of Regulatory Affairs, District Field Office
8
Please select
Original ICSR Number
1200015
* Inital Report Date
10/25/2012
Save Draft
Exit
Submit Report
Next>
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
1254452
Duplicate report
1254456
Parent offspring
Add
Edit


Unique AER identification number for linked reports
Unique AER identification number for linked report
*Explanation for Linkage
Please select
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 — Please select
* Street Address Line 1
* City/Town
* State — Please select
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? O Yes O No O Unknown

Business Name
*First name
*Last name
Title
* Email
* Confirm email
*Phone
Fax

Regulatory Authority (RA)

* Regulatory Authority Name — Food and Drug Administration, Center for Veterinary Medicine
* Country — United States
* Street Address Line 1 — 7500 Standish Place (HFV-199), Room 403
* City/Town — Rockville
* State — Maryland
*Mail/Zip Code — 20855

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

Primary Reporter

*Reporter Category
- (•) Veterinarian
- ( ) Animal Owner
- ( ) Physician
- ( ) Patient
- ( ) Other Health Care Professsional
- ( ) Unknown
- ( ) Other

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

First Name
*Last Name
Email
Confirm email
Phone
Fax
Business Name
*Country — Please select
Street Address Line 1
City/Town
State — Please select
State/Province
Mail/Zip Code

Is there another reporting source? O Yes O No

Other Reporter

*Reporter Category
- (•) Veterinarian
- ( ) Animal Owner
- ( ) Physician
- ( ) Patient
- ( ) Other Health Care Professsional
- ( ) Unknown
- ( ) Other

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

First Name
Last Name
Email
Confirm email
Phone
Fax
Business name
Country — Please select
Street Address Line 1
City/Town
State — Please select
State/Province
Mail/Zip Code

Save Draft | Exit | Submit Report | < Back | Next>

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Problem Summary

* =Required

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

Animal Information

Number of Animals Treated (1)

*Number of Animals Affected

*Species (2) Please select

Are there any purebred animals? O Yes O No O Unknown

Purebred Animals

Click on the Add button to add a breed

Add | Edit | Delete | I< <Page 1 of 1 > >I

Purebred Animals

O Landrace- German
O Pietrain

Add | Edit | I< <Page 1 of 1 > >I

Are there any crossbred animals? O Yes O No O Unknown

Crossbred Animals

Click on the Add button to add a breed

Add | Edit | Delete | I< <Page 1 of 1 > >I

Crossbred Animals

O Retriever- Golden
O Hound (unspecified)

Add | Edit | I< <Page 1 of 1 > >I

Gender: Please select

Reproductive Status (3): Please select

Female Physiological Status: Please select

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

*Minimum Age: Select Unit of Measure

Maximum Age: Select Unit of Measure

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

*Minimum Weight: Select Unit of Measure

Maximum Weight: Select Unit of Measure

Attending Veterinarian's Assessment of Animal Health Status Prior to Administering the Product: O Excellent O Good O Fair O Poor O Critical O Unknown O No Attending Veterinarian

Problem Description

* Narrative of Adverse Event/Product Problem

ABC

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

Duration of Adverse Event: Select Unit of Measure

Length of time between exposure to Product and Onset of Adverse Event: Please select

Were the symptoms treated? O Yes O No O Unknown

*Was the adverse event serious? O Yes O No

*Adverse Clinical Manifestations

VeDDRA Terms	Number of Animals	Accuracy
Click on the Add button to add a term		

Add | Edit | Delete | I< <Page 1 of 1 > >I

VeDDRA Terms	Number of Animals	Accuracy
O Chronic Renal Failure	2	Estimated

Add | Edit | Delete | I< <Page 1 of 1 > >I

FDA Product Problem Terms	Number of Animals	Accuracy
Click on the Add button to add a term		

Add | Edit | Delete | I< <Page 1 of 1 > >I

FDA Product Problem Terms	Number of Animals	Accuracy
O Tablets, Abnormal	1	Actual

Add | Edit | Delete | I< <Page 1 of 1 > >I

FDA Adverse Event Terms	Number of Animals	Accuracy
Click on the Add button to add a term		

Add | Edit | Delete | I< <Page 1 of 1 > >I

FDA Adverse Event Terms	Number of Animals	Accuracy
O INEFFECTIVE, HEARTWORM ADULTS	3	Actual

Add | Edit | Delete | I< <Page 1 of 1 > >I

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

Save Draft | Exit | Submit Report

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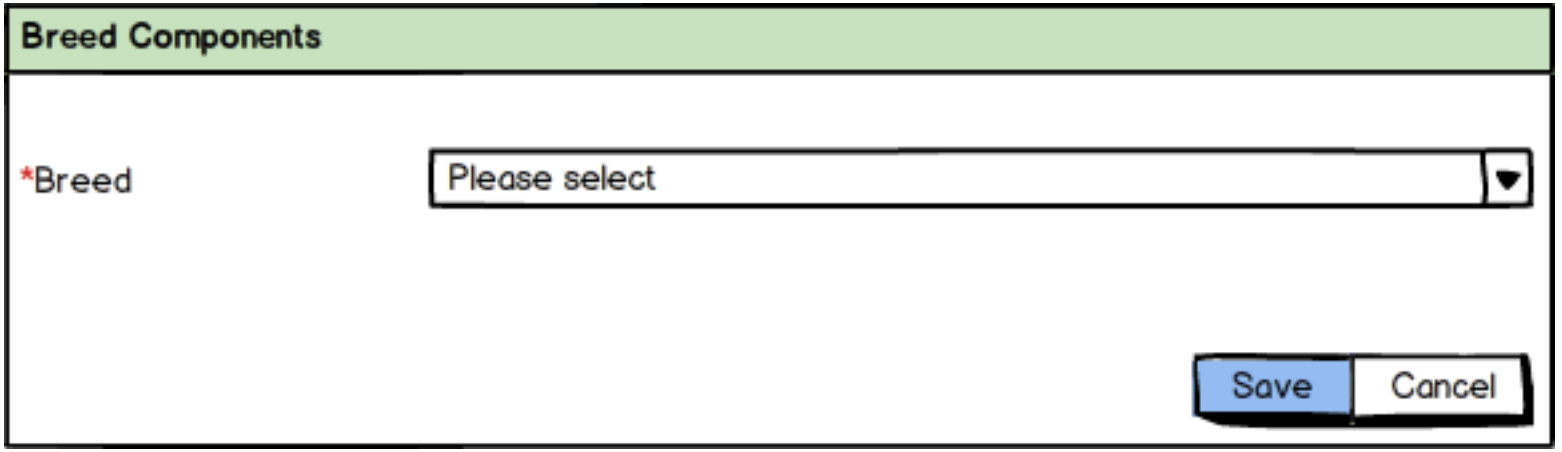
Breed Components
*Breed
Please select
Save
Cancel

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)?	O Yes	O No	O Unknown	O Not Applicable
Did the adverse event reappear after reintroducing the VMP(s) ?	O Yes	O No	O Unknown	O Not Applicable

Attending Veterinarian's assessment of the association between the VMP(s) and the adverse event

- (•) Probable
- O Possible
- O Unlikely
- O Unknown
- O No Assessment
- O No Attending Veterinarian

Product Details

*Product Details

Product Name	Marketing Authorization Holder	Registration ID
Click on the Add button to add an item		

Add | Edit | Delete

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	

Add | Edit | Delete

*Ingredient detail for <product name>

Active Ingredient Name	AI Code	Strength (numerator)	UOM	Strength
Click on the Add button to add an item				

Add | Edit | Delete

Dosing schedule for <product name>

Dose	UOM	Route	First Exposure	Last Exposure
Click on the Add button to add an item				

Add | Edit | Delete

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					

Add | Edit | Delete

Save Draft | Exit | Submit Report

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*Product Details

Product Name	Marketing Authorization Holder	Registration ID
(•) Flex-Joint	usa-Pharm	USA-gooddrug-Z778556
O joint relief	UAT	USA-baddrugs-N445856

Add | Edit | Delete | I< <Page 1 of 1 > >I

Regulatory Authority Assessment Term

Regulatory Authority Assessment Term	Explanation
O Probable	Highly likely VMP caused the AE

Add | Edit

Ingredient detail for Flex-Joint

Active Ingredient Name	Code	Strength (numerator)	UOM	Strength (denominator)	UOM
O glucosomine	glc	5	Milligram	1	liter

Add | Edit | Delete | I< <Page 1 of 1 > >I

Dosing schedule for Flex-Joint

Dose	UOM	Route	First Exposure	Last Exposure
O 1	capsule	ORAL	9/5/2012	9/12/2012

Add | Edit | Delete | I< <Page 1 of 1 > >I

Product lots for Flex-Joint

Lot#	Exp. Date	Manuf.SiteID/Type	Manuf. Date	No. defective items	No.returned items
O 457	10/31/2014	1234564 DUNS	10/31/2012	251	250

Add | Edit | I< <Page 1 of 1 >

Product Details

*Registered or Brand Name

ABC

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

Company or MAH

ABC

*Country Where Drug was Approved: Please select

*Regulatory Authority Identifier: Please select

*Registration Number (1)

*Registration Identifier (2)

Product Code (3)

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

ABC

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

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

(4)

* Anatomical Therapeutic Chemical Vet (ATCVet) Code

Dosage Form: Please select

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

Explanantion for Off-Label Use:

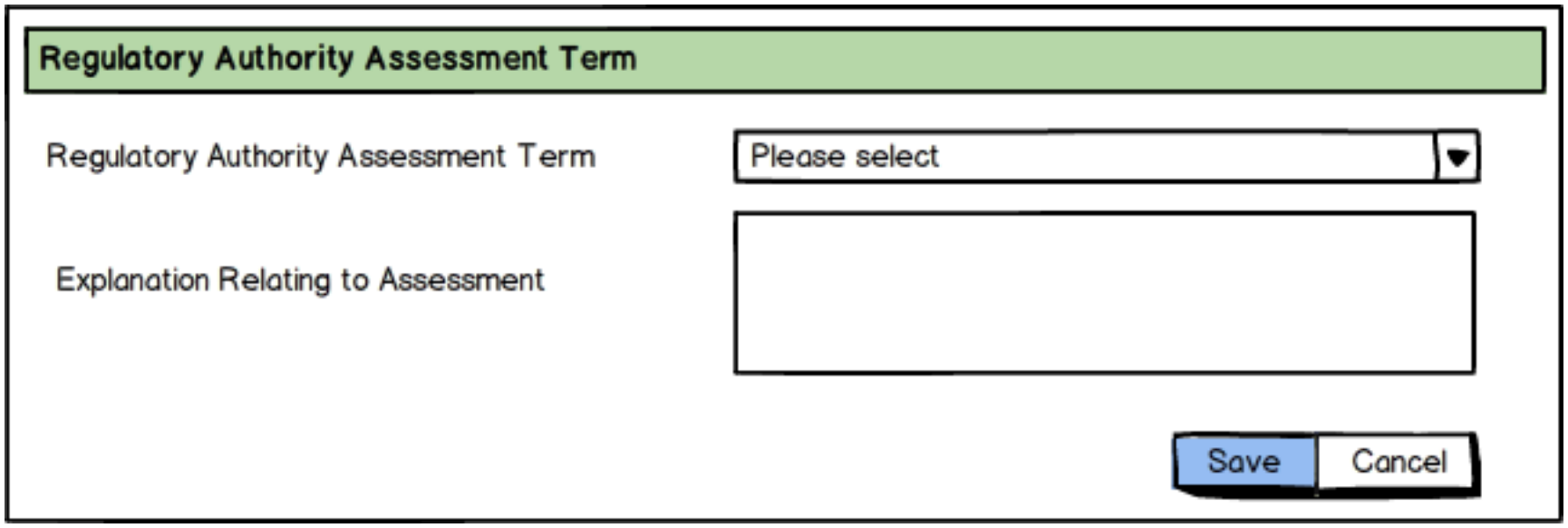
- Was the target species off-label? ☐
- Was the route of administration off-label? ☐
- Was the animal overdosed? ☐
- Was the animal underdosed? ☐
- Was the treatment regimen off-label? ☐
- Was the indication off-label? ☐
- Was the storage condition off-label? ☐
- Was the product expired? ☐
- Was there any other off-label issue? ☐

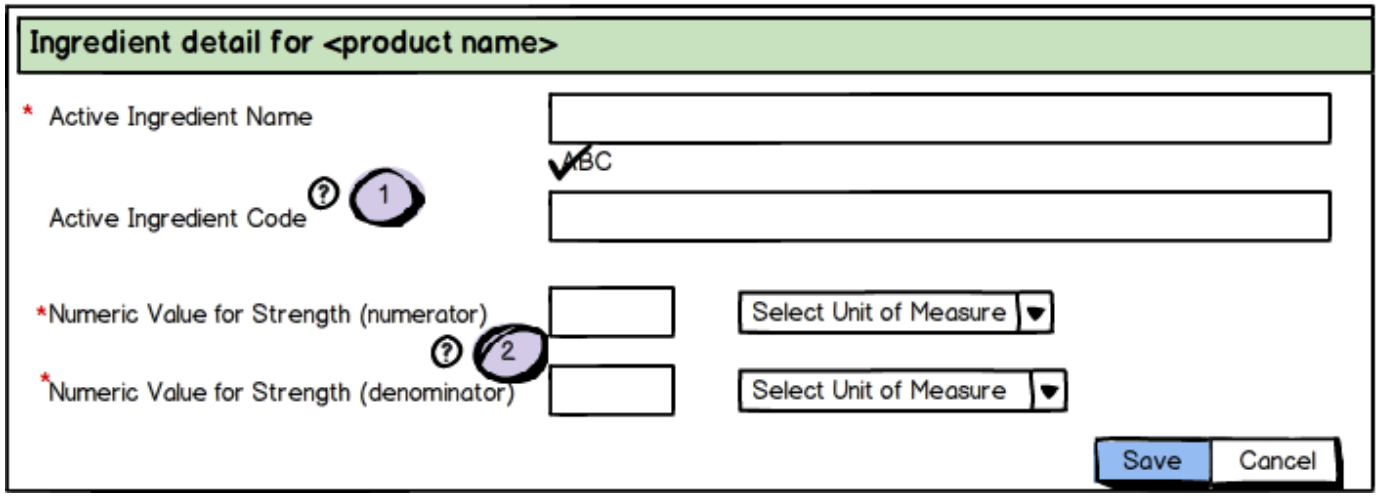
Who administered the VMP?

- (•) Veterinarian
- O Animal Owner
- O Physician
- O Patient
- O Other Health Care Professional
- O Multiple Administrators
- O Other
- O Unknown

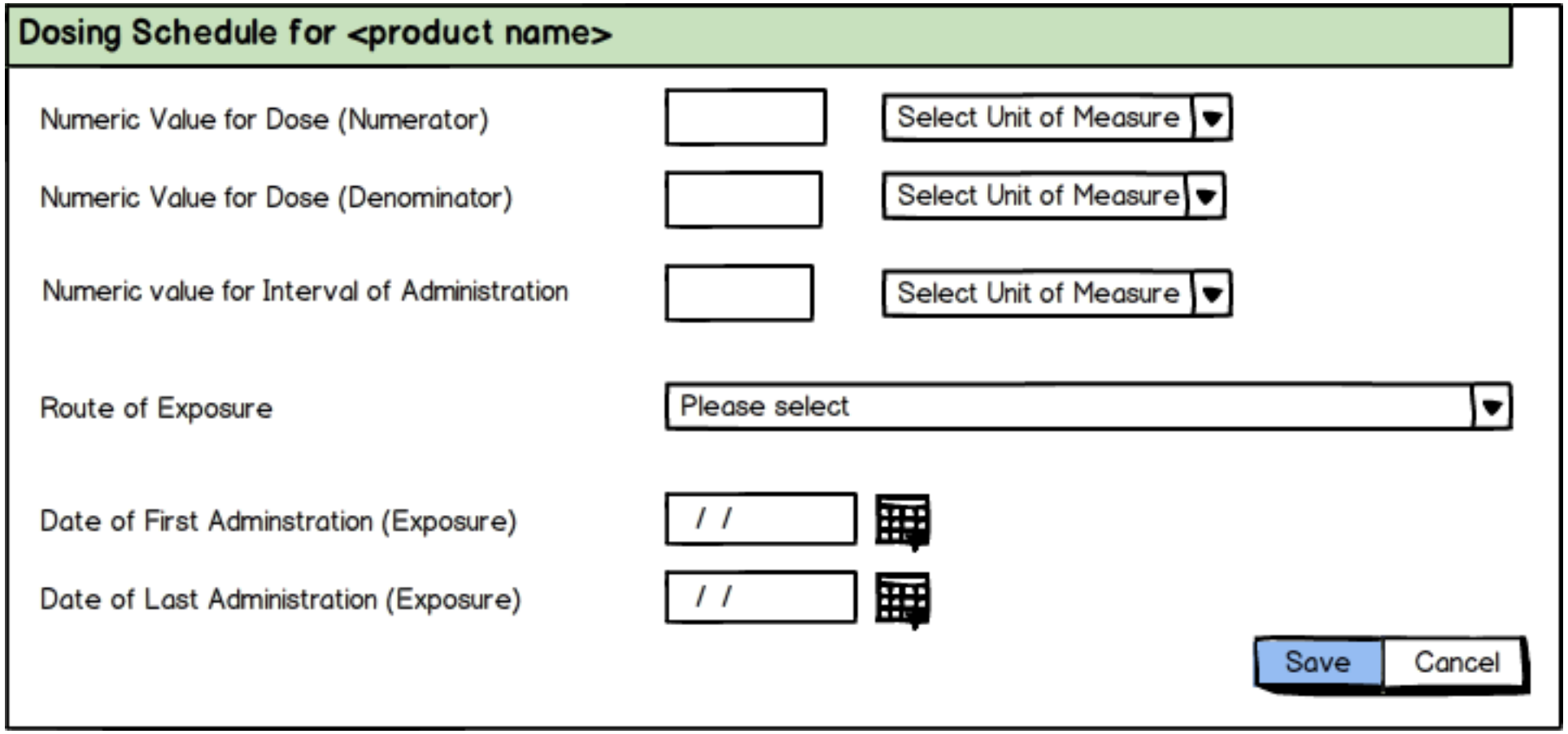
Save Cancel

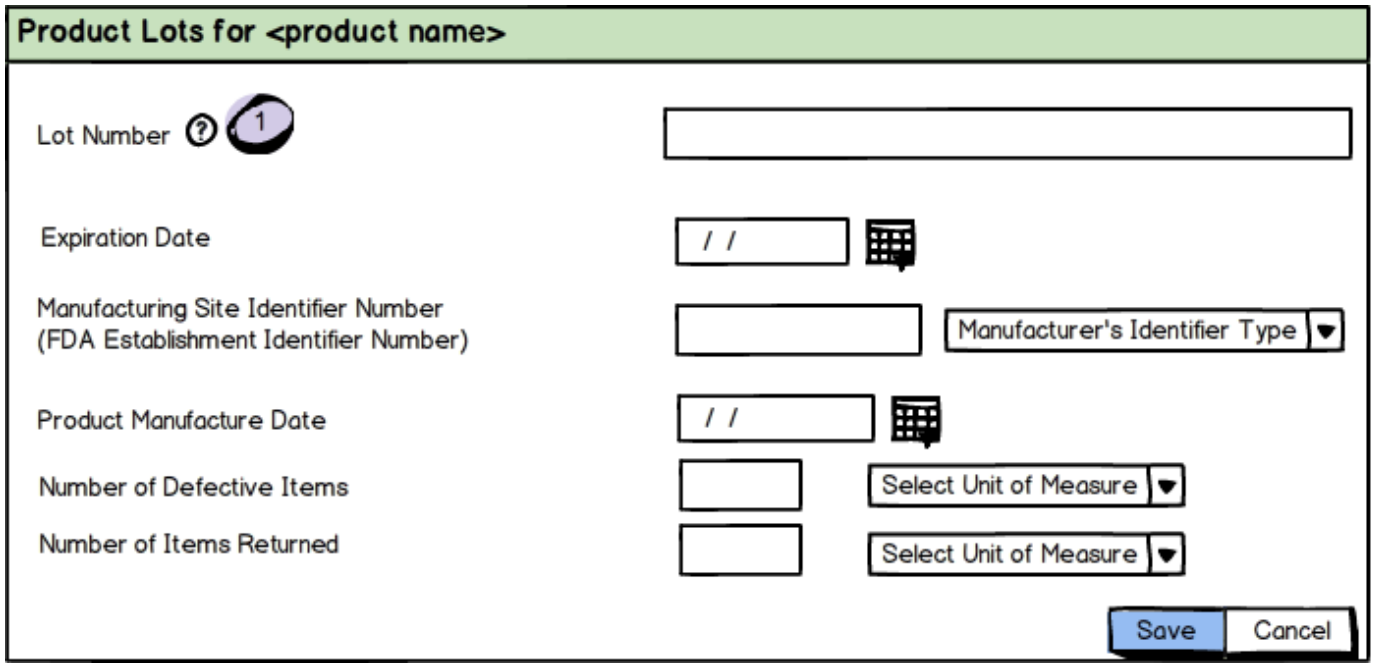
1)Refer to the Guidance for Industry #188, section A.1
2))Refer to the Guidance for Industry #188, section B.2.1.2
3))Refer to the Guidance for Industry #188, section B.2.1.1
4)Refer to the Guidance for Industry #188, section B.2.1.3


Regulatory Authority Assessment Term
Regulatory Authority Assessment Term
Please select
Explanation Relating to Assessment
Save
Cancel

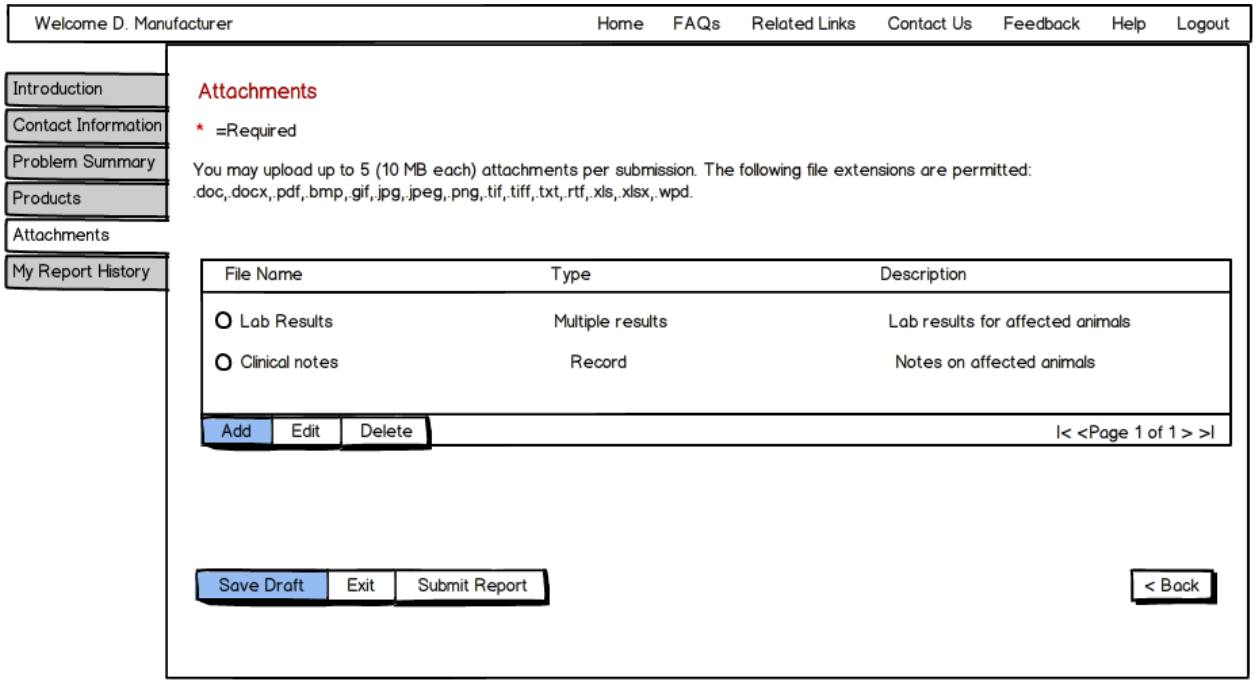


1)Refer to the Guidance for Industry #188, section B.2.2.1.2
2)Refer to the Guidance for Industry #188, section B.2.2.1.1


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
Please select
Date of First Adminstration (Exposure)
/ /
Date of Last Administration (Exposure)
/ /
Save
Cancel



1) Lot number is typically a string of numbers located near the expiration/use-by date.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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
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Lab results for affected animals
Clinical notes
Record
Notes on affected animals
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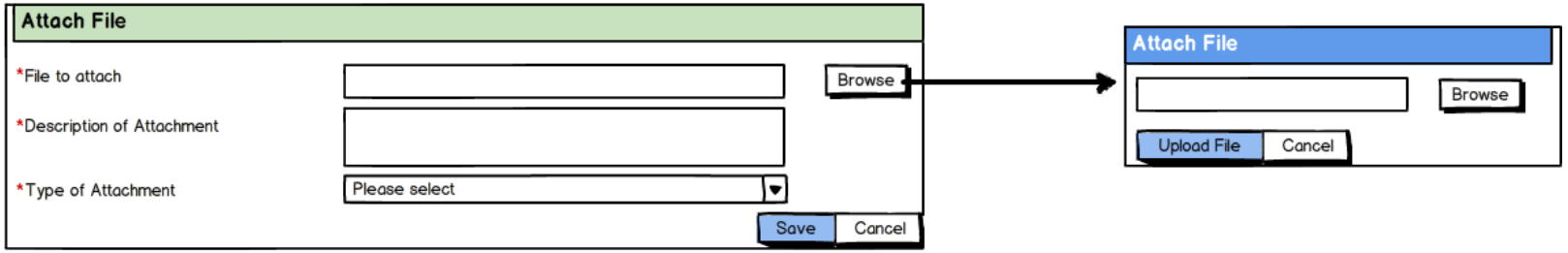
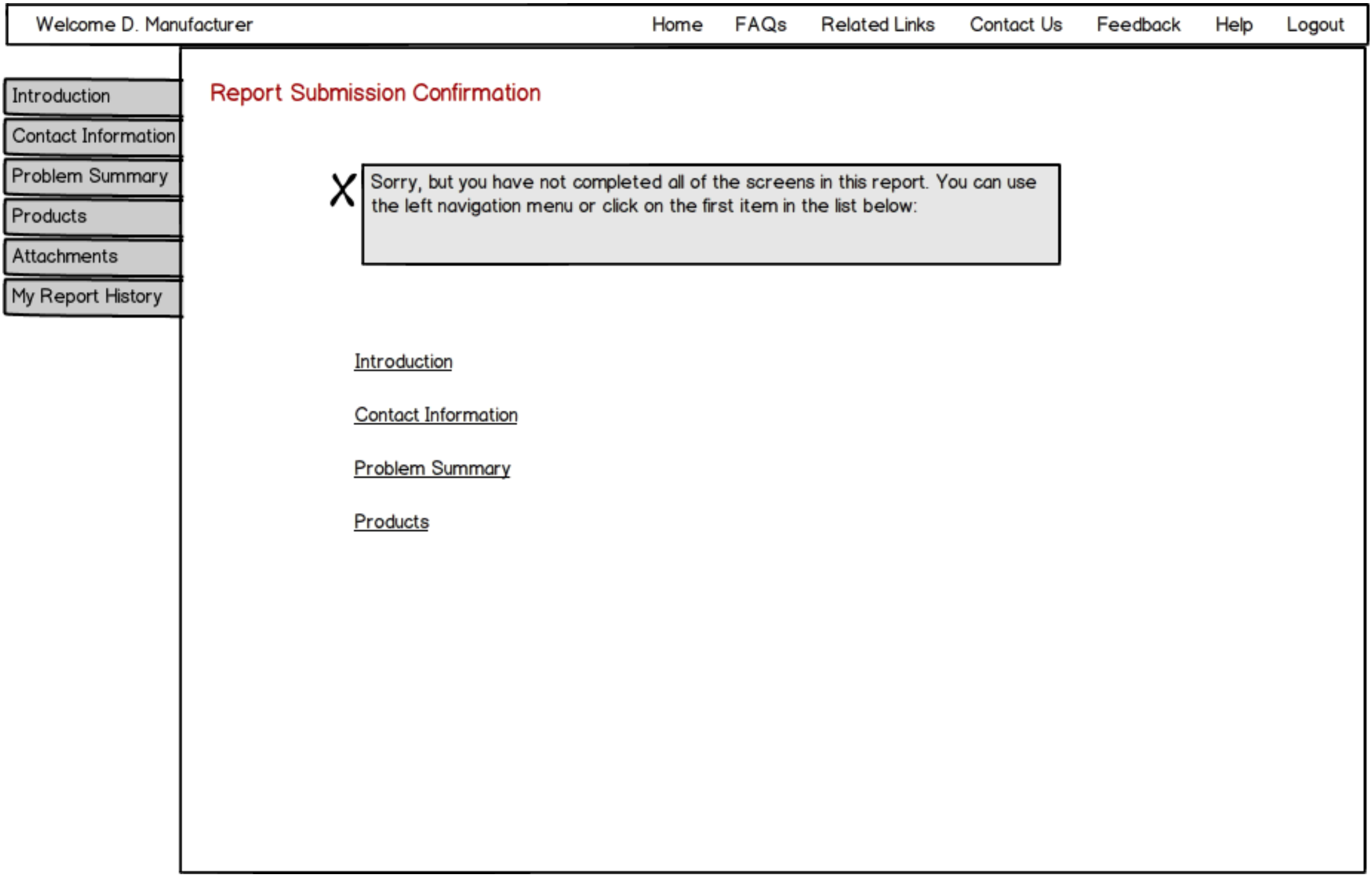

Attach File
*File to attach
Browse
*Description of Attachment
*Type of Attachment
Please select
Save
Cancel
Attach File
Browse
Upload File
Cancel

*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X
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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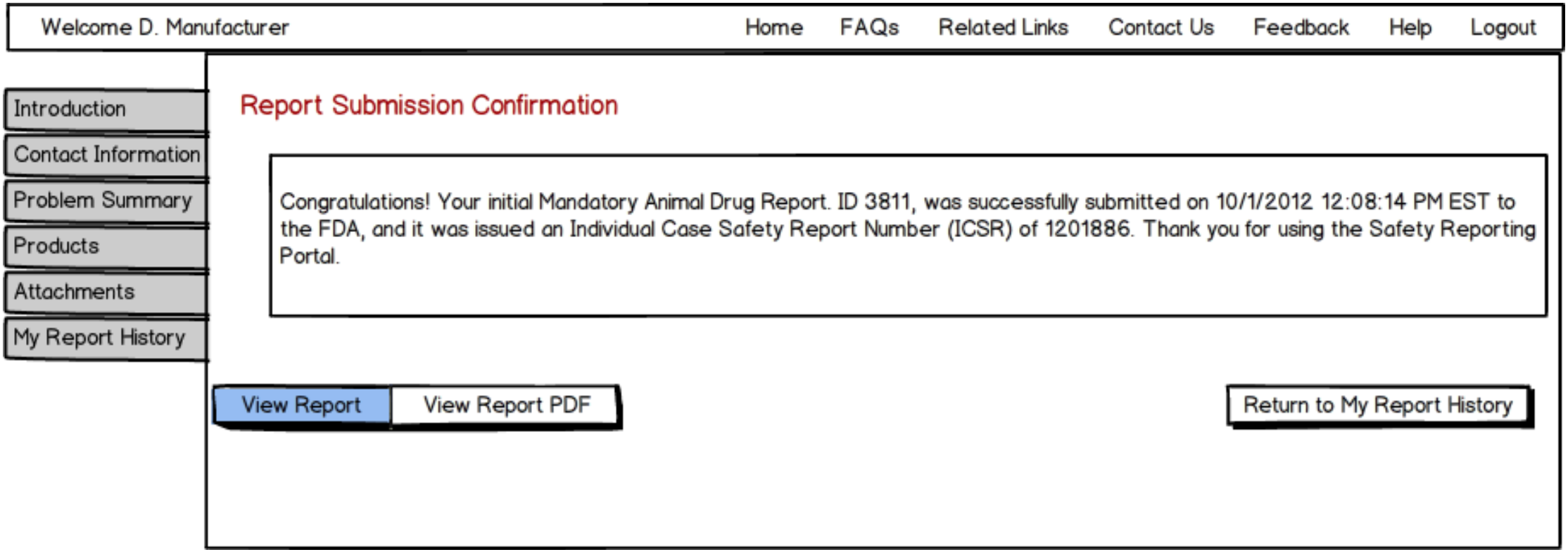
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Report Submission Confirmation
Congratulations! Your initial Mandatory Animal Drug Report. ID 3811, was successfully submitted on 10/1/2012 12:08:14 PM EST to the FDA, and it was issued an Individual Case Safety Report Number (ICSR) of 1201886. Thank you for using the Safety Reporting Portal.
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JBS International, Inc.
5515 Security Lane, Suite 800
North Bethesda, MD 20852