Safety Reporting Portal

ABOUT THE PORTAL | SAFETY REPORT DIRECTORY | FAQS | RELATED LINKS | CONTACT US

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
·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

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.

HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

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	
* Last 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

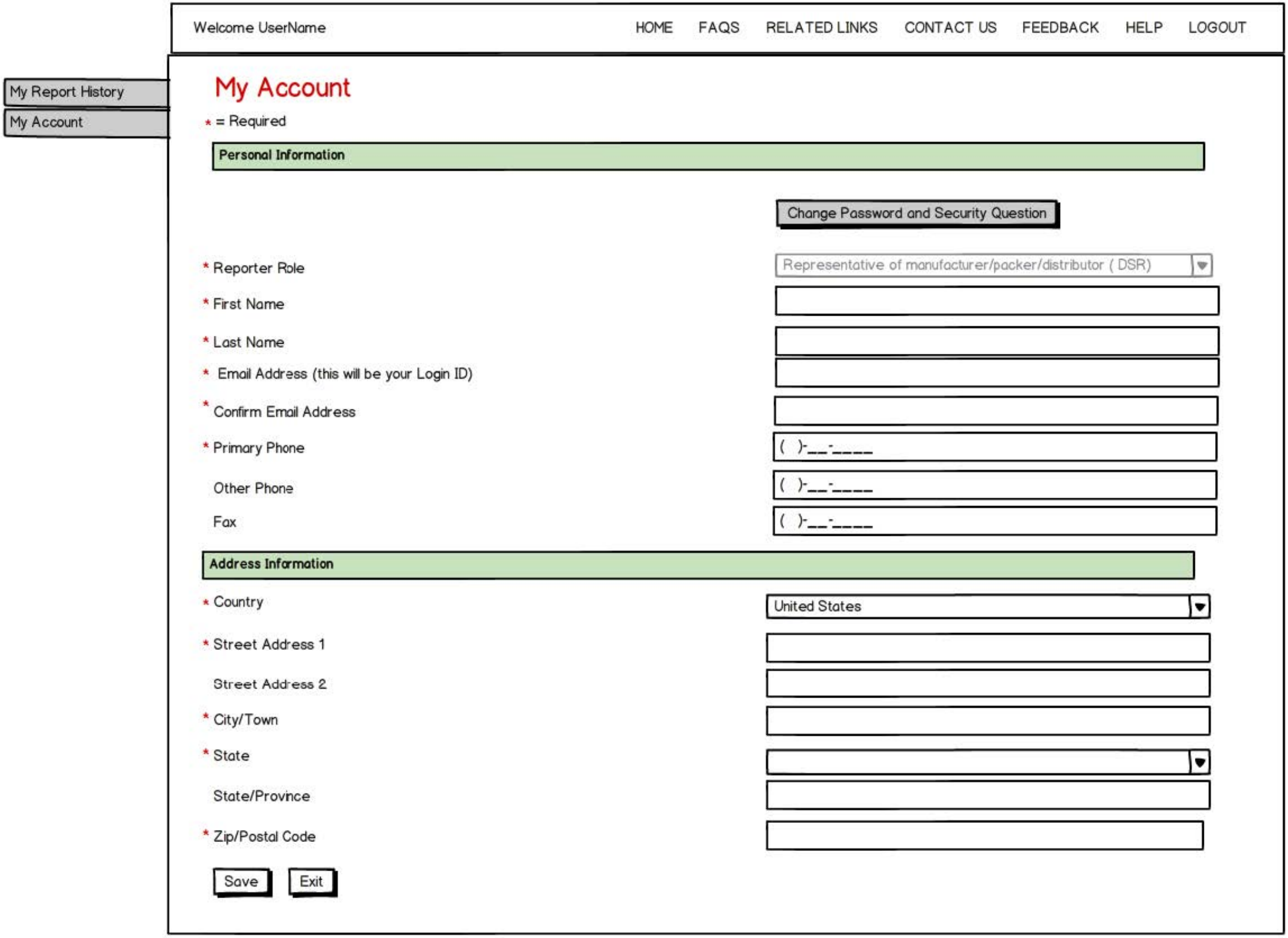
* Email Address (this will be your login ID)	
* Confirm Email Address	

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 UserName
HOME
FAQS
RELATED LINKS
CONTACT US
FEEDBACK
HELP
LOGOUT
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

Welcome Guest | Home | FAQs | Related Links | Contact Us | Feedback | Help | Logout

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

[Begin Report] [Exit]

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- ( ) A consumer or concerned citizen who is submitting a product problem and/or adverse event involving pet food.
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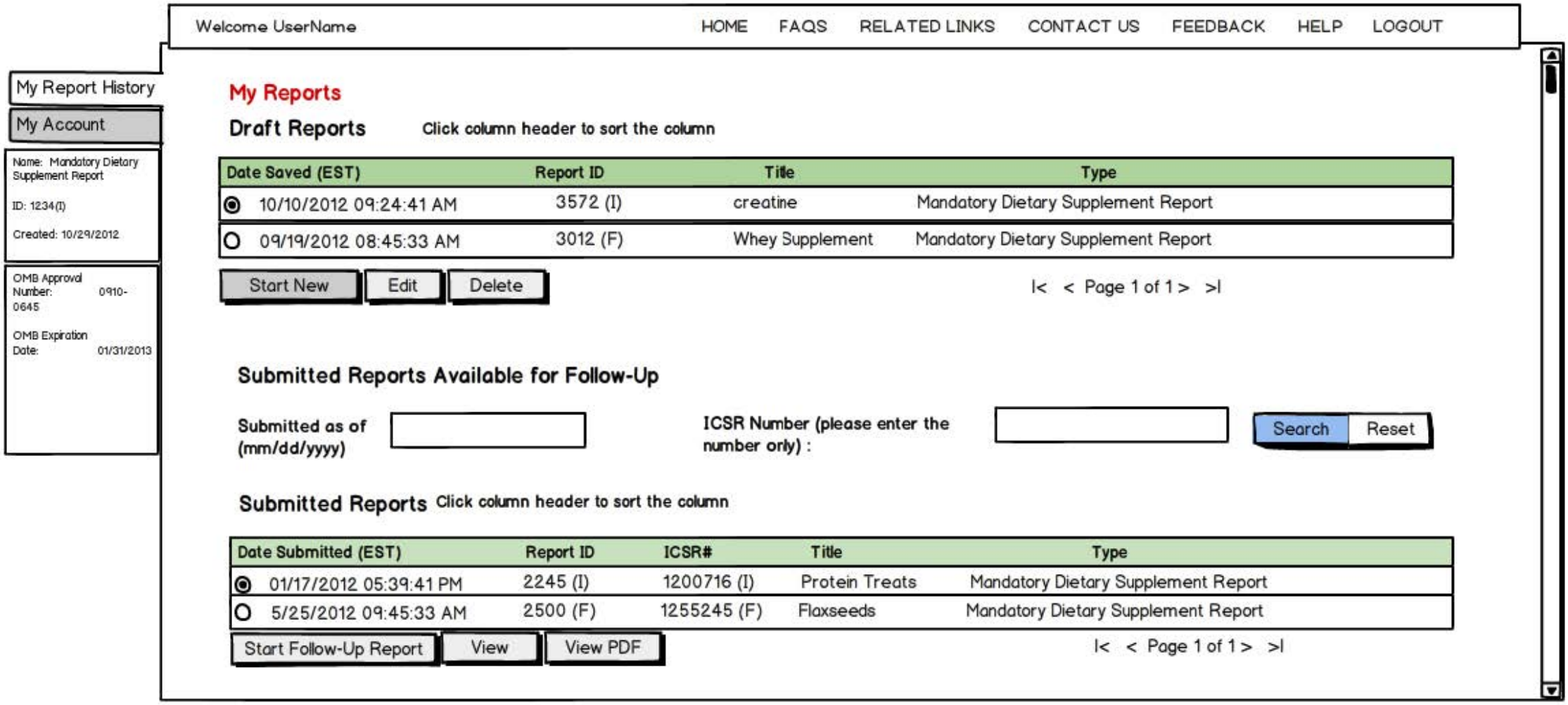
- ( ) None of these describe me.

[Begin Report] [Exit]


Welcome UserName
HOME
FAQS
RELATED LINKS
CONTACT US
FEEDBACK
HELP
LOGOUT
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
10/10/2012 09:24:41 AM
3572 (I)
creatine
Mandatory Dietary Supplement Report
09/19/2012 08:45:33 AM
3012 (F)
Whey Supplement
Mandatory Dietary Supplement Report
Start New
Edit
Delete
I< < Page 1 of 1 > >I
Submitted Reports Available for Follow-Up
Submitted as of (mm/dd/yyyy)
ICSR Number (please enter the number only) :
Search
Reset
Submitted Reports
Click column header to sort the column
Date Submitted (EST)
Report ID
ICSR#
Title
Type
01/17/2012 05:39:41 PM
2245 (I)
1200716 (I)
Protein Treats
Mandatory Dietary Supplement Report
5/25/2012 09:45:33 AM
2500 (F)
1255245 (F)
Flaxseeds
Mandatory Dietary Supplement Report
Start Follow-Up Report
View
View PDF
I< < Page 1 of 1 > >I

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

blue text = conditional field

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

OMB Approval Number: 0910-0645

OMB Expiration Date: 01/31/2013

Introduction

* =Required

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, 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. 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.

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?

- O Serious adverse event (a serious adverse health-related event associated with the product)
- O 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

< Back | Next >

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

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- Contact Information
- Problem Summary
- Products
- Concomitant Products
- Attachments
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- ☐ Friend or Relative
- ☐ Distributor
- ☐ Health Professional
- ☐ Lawyer
- ☐ Social Media
- ☐ Other

If other, please describe [ ]

Orignal ICSR number [2354363463] →

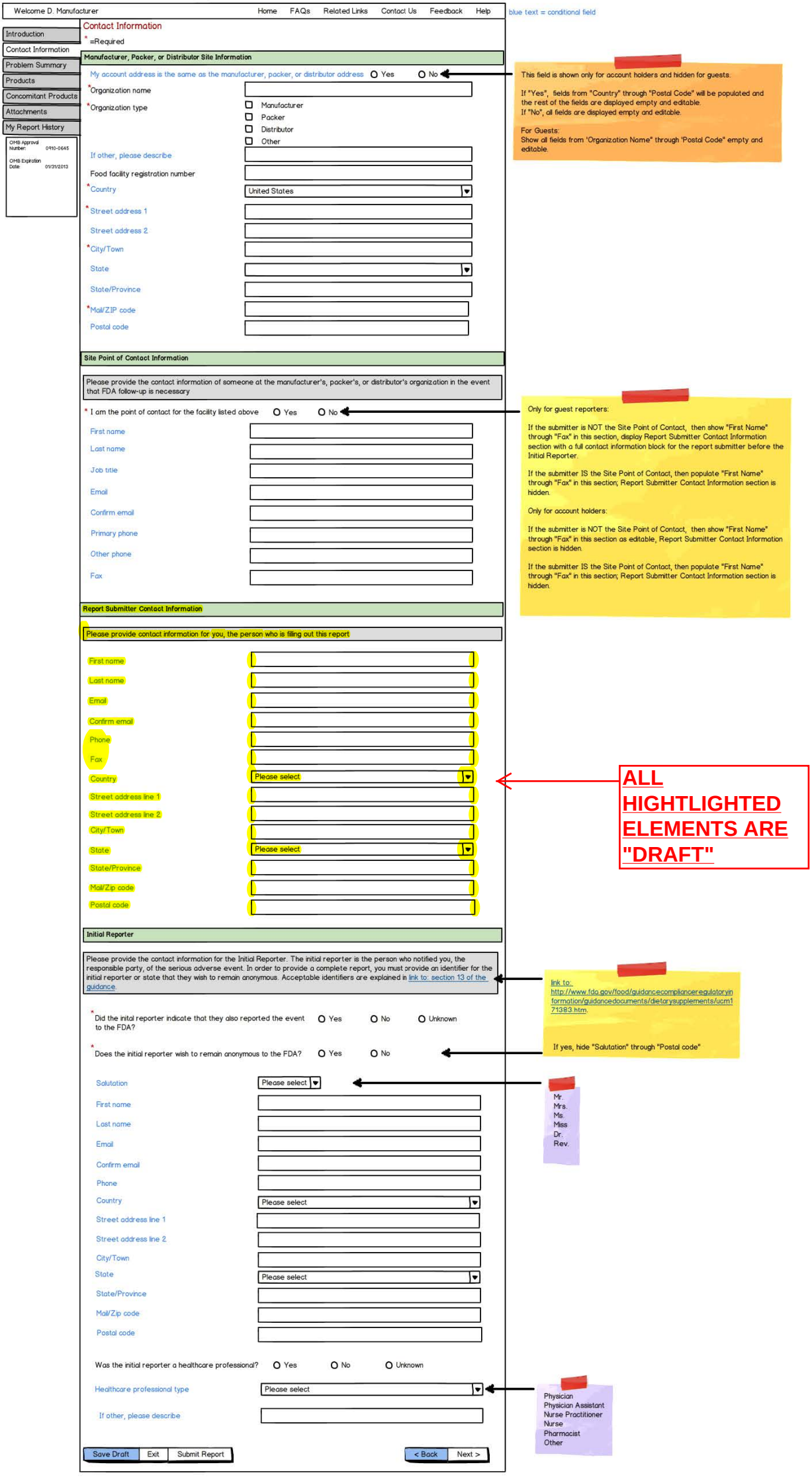
Initial report date [03/ 01 /2013] →

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

* Reason for follow-up [ ]

Save Draft | Exit | Submit Report

< Back | Next >


Welcome D. Manufacturer
Home
FAQs
Related Links
Contact Us
Feedback
Help
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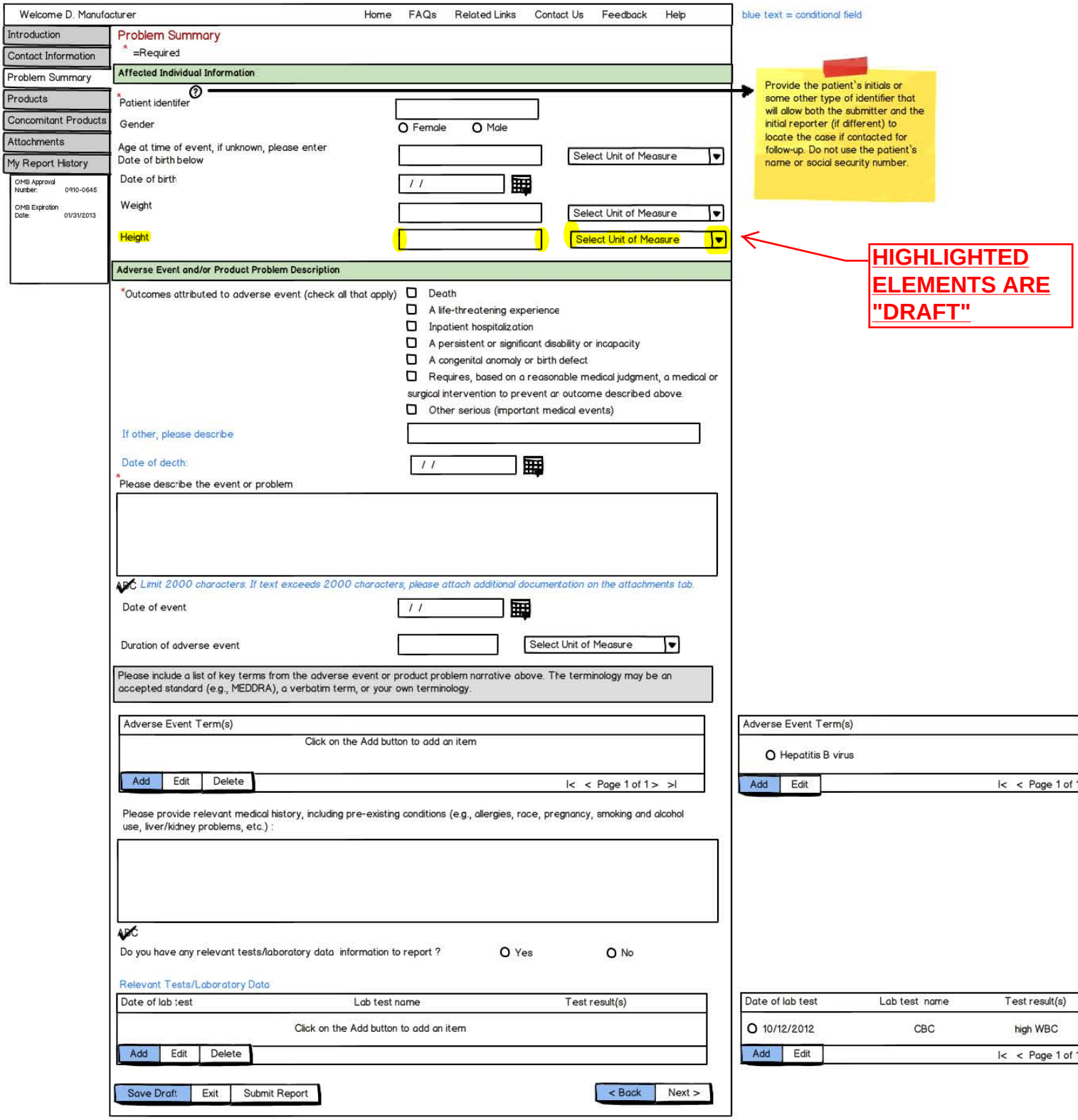
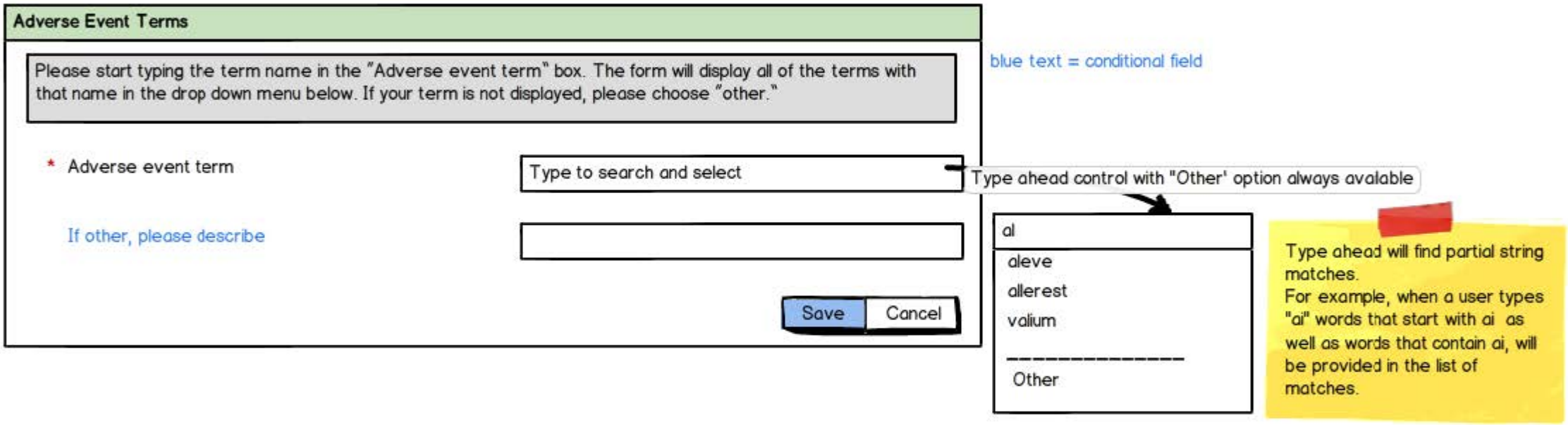
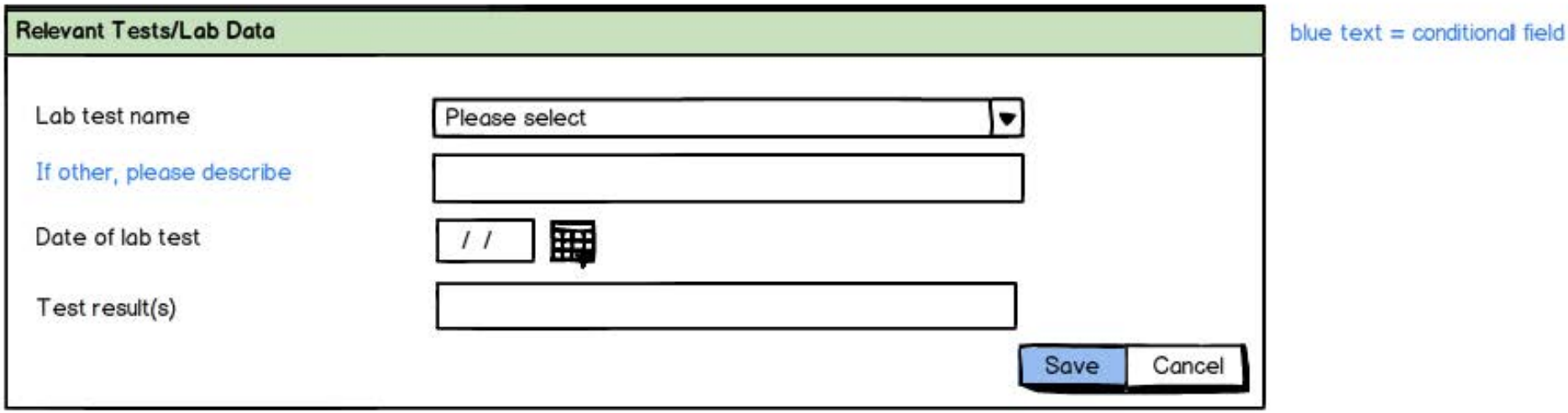
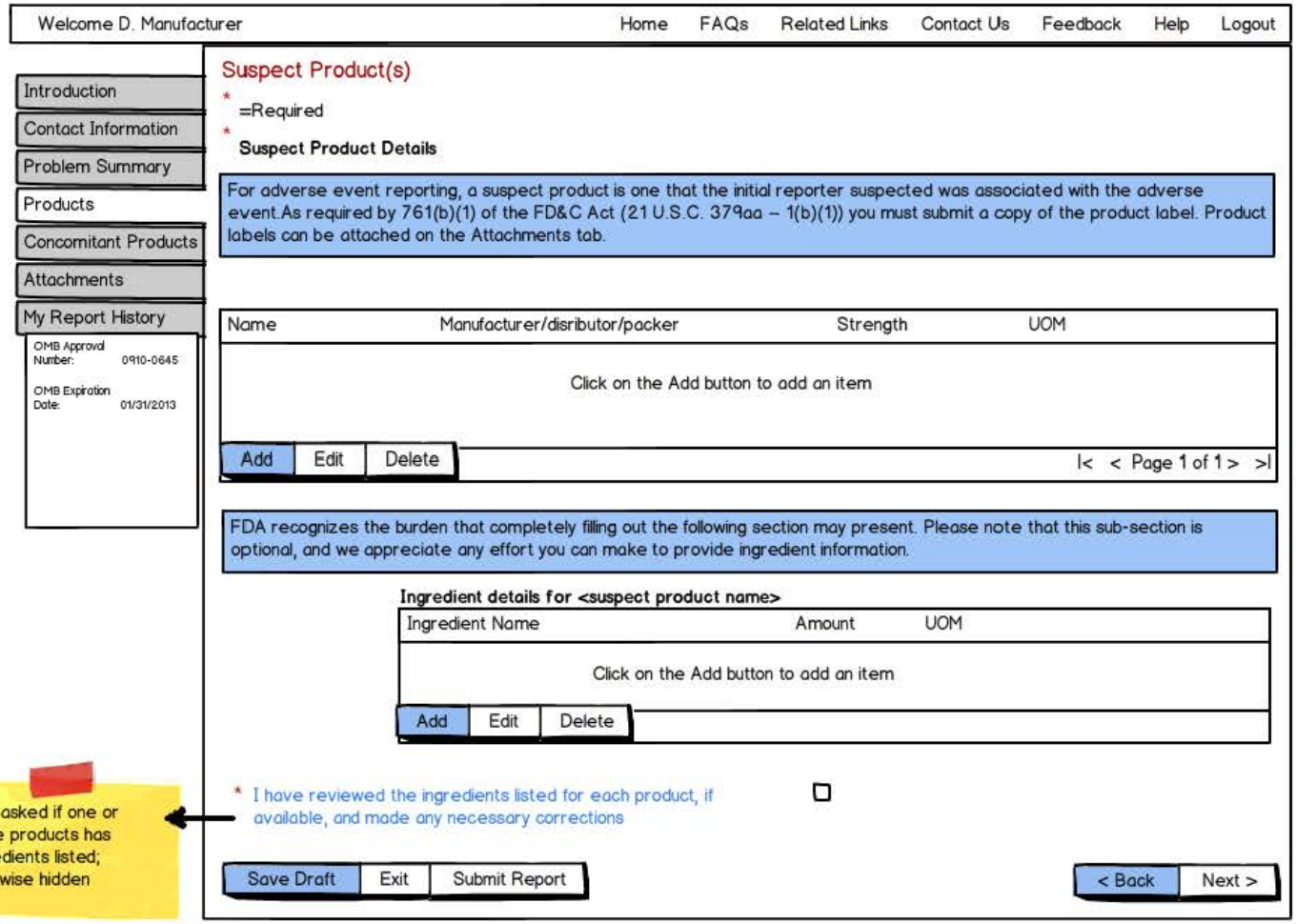
Introduction
Contact Information
Problem Summary
Products
Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
Contact Information
* =Required
Manufacturer, Packer, or Distributor Site Information
My account address is the same as the manufacturer, packer, or distributor address
Yes
No
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.
*Organization name
*Organization type
Manufacturer
Packer
Distributor
Other
If other, please describe
Food facility registration number
*Country
United States
*Street address 1
Street address 2
*City/Town
State
State/Province
*Mail/ZIP code
Postal code
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
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.
First name
Last name
Job title
Email
Confirm email
Primary phone
Other phone
Fax
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
Please select
Street address line 1
Street address line 2
City/Town
State
Please select
State/Province
Mail/Zip code
Postal code
ALL HIGHTLIGHTED 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.
link to: http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/dietarysupplements/ucm171383.htm.
* Did the inital 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
If yes, hide "Salutation" through "Postal code"
Salutation
Please select
Mr.
Mrs.
Ms.
Miss
Dr.
Rev.
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
Was the initial reporter a healthcare professional?
Yes
No
Unknown
Healthcare professional type
Please select
Physician
Physician Assistant
Nurse Practitioner
Nurse
Pharmacist
Other
If other, please describe
Save Draft
Exit
Submit Report
< Back
Next >


Welcome D. Manufacturer
Home
FAQs
Related Links
Contact Us
Feedback
Help
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
Problem Summary
* =Required
Affected Individual Information
*Patient identifer
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.
Gender
Female
Male
Age at time of event, if unknown, please enter Date of birth below
Select Unit of Measure
Date of birth
/ /
Weight
Select Unit of Measure
Height
Select Unit of Measure
HIGHLIGHTED ELEMENTS ARE "DRAFT"
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 ar outcome described above.
Other serious (important medical events)
If other, please describe
Date of decth:
/ /
*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
Add
Edit
Delete
I< < Page 1 of 1 > >I
Adverse Event Term(s)
Hepatitis B virus
Add
Edit
I< < Page 1 of 1 > >I
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 :est
Lab test name
Test result(s)
Click on the Add button to add an item
Add
Edit
Delete
Date of lab test
Lab test name
Test result(s)
10/12/2012
CBC
high WBC
Add
Edit
I< < Page 1 of 1 > >I
Save Draft
Exit
Submit Report
< Back
Next >


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 avalable
al
aleve
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.



blue text = conditional field



blue text = conditional field

Grid view after products are added

Name	Manufacturer/disributor/packer	Strength	UOM
O Joint-Ease	ABC	150	mg

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

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

Ingredient Name	Amount	UOM
O Ibuprofen	300	mg
O Vitamin D	200	g
O Calcium	45	mg
O Vitamin B12	10	ug

Add Edit I< < 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

Partial matches at the beginning and within terms are included

al
aleve
allerest
valium

Other

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):

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

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 — Please select

Frequency of consumption — Select Unit of Measure

Amount consumed per serving — Select Unit of Measure

Administration route — Please select

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

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

Please provide any 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 — Type to search and select

If other, please describe

Ingredient amount — Select Unit of Measure

Save | Cancel

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

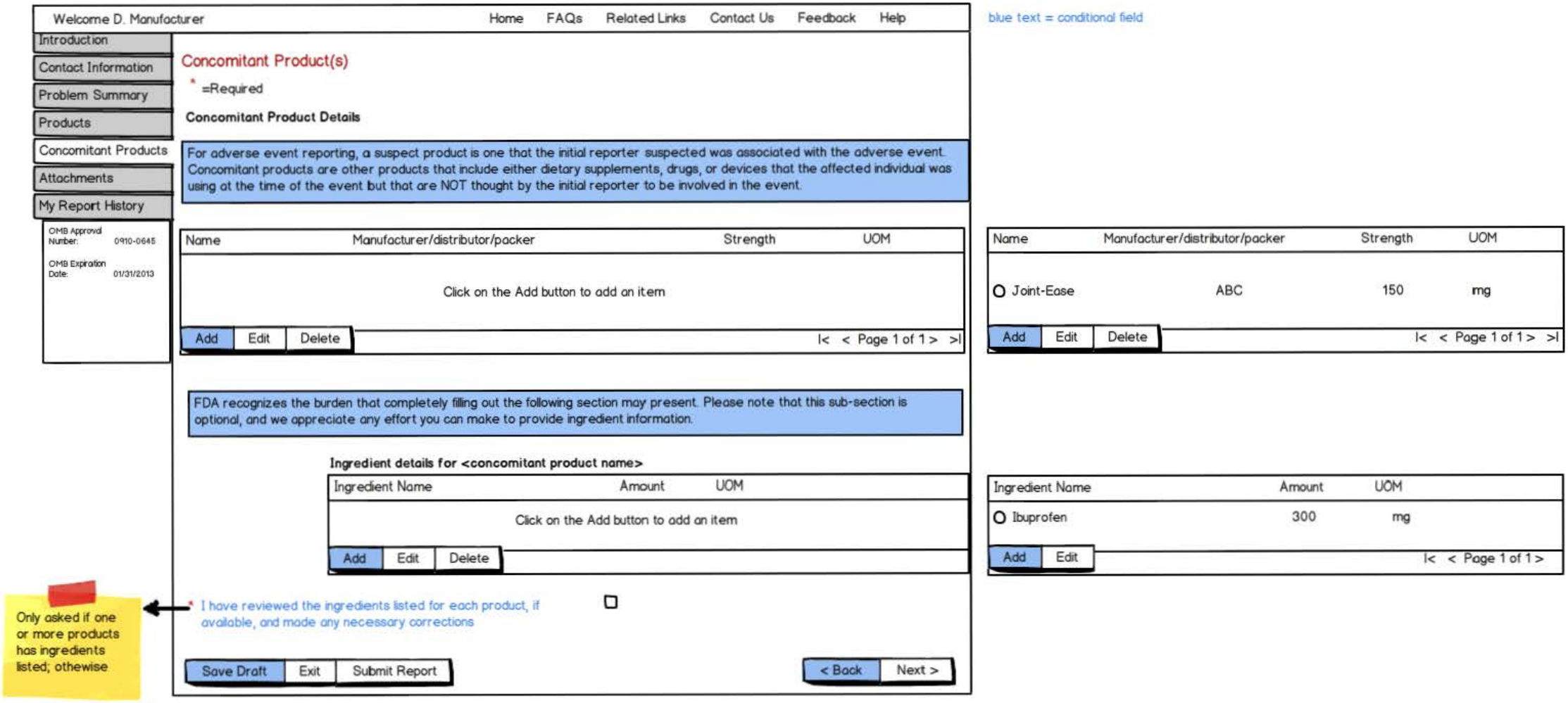
Edit Ingredient

Ingredient details for <suspect product name>

Ingredient name — Ibuprophen

Ingredient amount — 30 — milligrams (mg)

Save | Cancel


Welcome D. Manufacturer
Home
FAQs
Related Links
Contact Us
Feedback
Help
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
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
Add
Edit
Delete
I< < Page 1 of 1 > >I
Name
Manufacturer/distributor/packer
Strength
UOM
Joint-Ease
ABC
150
mg
Add
Edit
Delete
I< < Page 1 of 1 > >I
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
Add
Edit
Delete
Ingredient Name
Amount
UOM
Ibuprofen
300
mg
Add
Edit
I< < Page 1 of 1 >
* 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; othewise
Save Draft
Exit
Submit Report
< Back
Next >

Concomitant Product Details

blue text = conditional field

Please sart 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 reponsible 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 (?) — / /

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

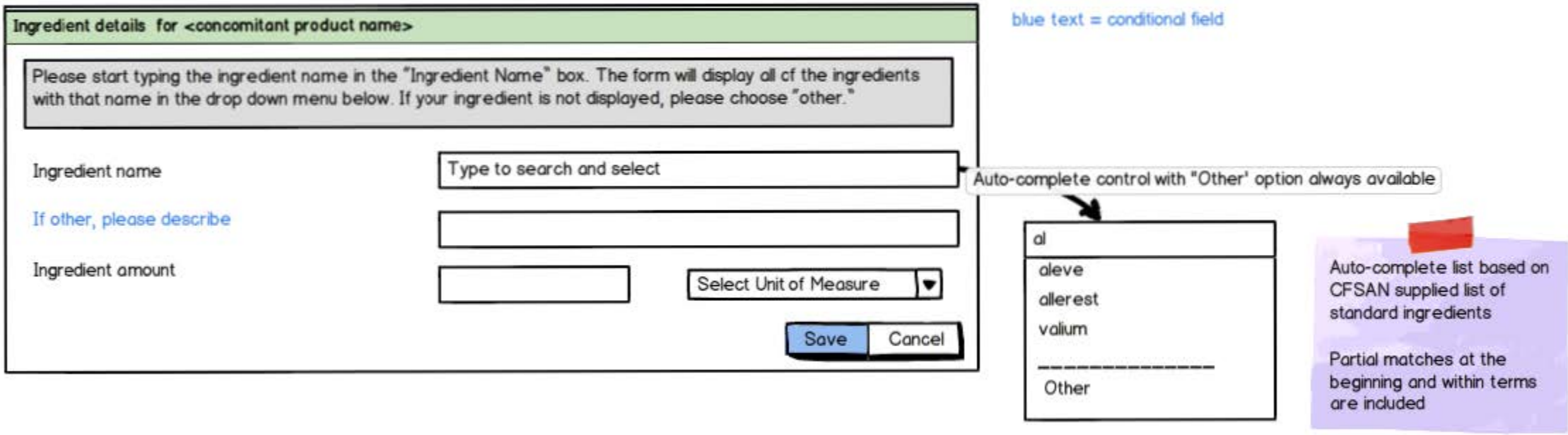
Amount consumed per serving — Select Unit of Measure

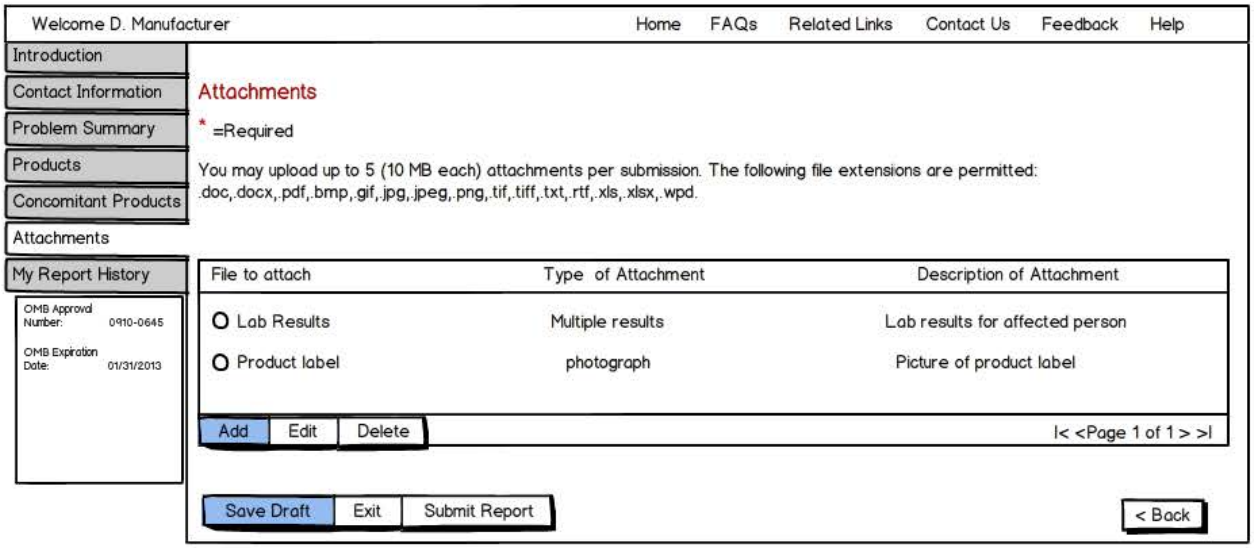
Administration route — Please select

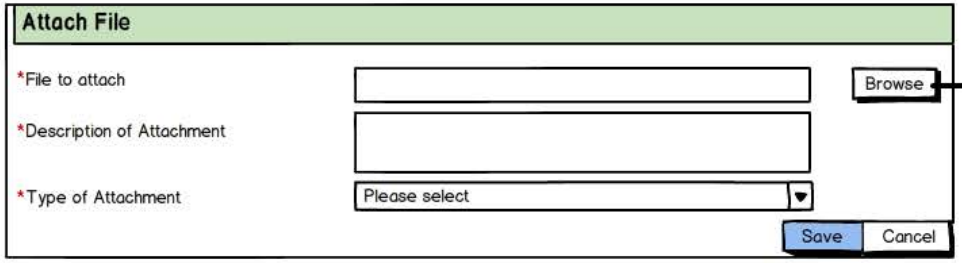
Please provide any notes describing the product's usage:

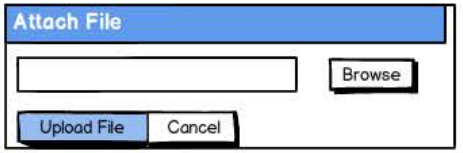
ABC

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
Type to search and select
If other, please describe
Ingredient amount
Select Unit of Measure
Save
Cancel
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


Welcome D. Manufacturer
Home
FAQs
Related Links
Contact Us
Feedback
Help
Introduction
Contact Information
Problem Summary
Products
Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
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
Lab Results
Multiple results
Lab results for affected person
Product label
photograph
Picture of product label
Add
Edit
Delete
I< <Page 1 of 1 > >I
Save Draft
Exit
Submit Report
< Back


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


Attach File
Browse
Upload File
Cancel

*

Introduction
Contact Information
Problem Summary
Products
Concomitant Products
Attachments
My Report History

Report Submission Confirmation

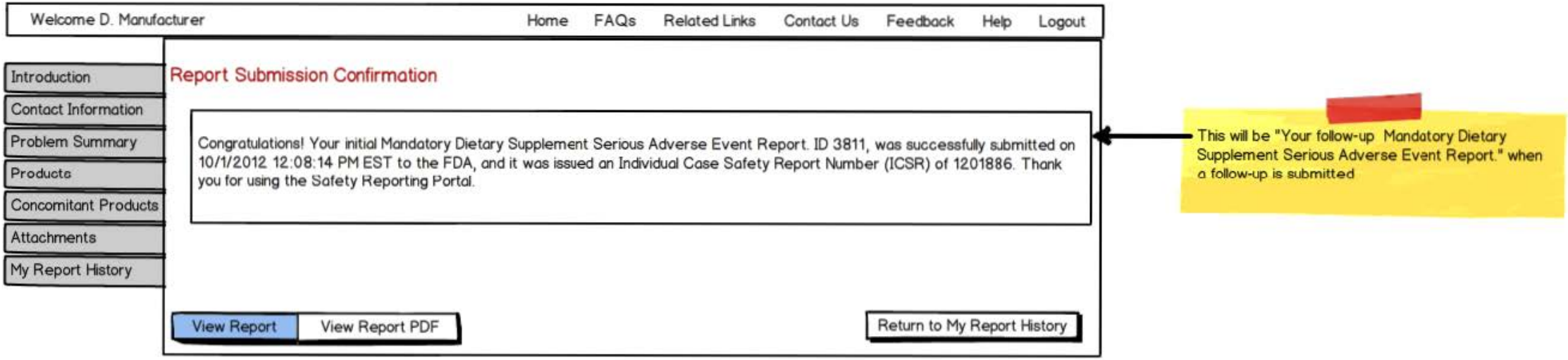
X Sorry, but you have not completed all of the required questions in this report.
You can use the left navigation menu or click on the first item in the list below:

Introduction

Contact Information

Problem Summary

Products


Welcome D. Manufacturer
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
Introduction
Contact Information
Problem Summary
Products
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