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.

Account Registration

*=Required

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

- O A food facility or responsible party that manufactures, processes, packs, or holds food who is submitting a reportable food report.
- O A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food
- O A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving pet food
- O A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving pet food
- O A marketing authorization holder (manufacturer) for an animal drug who is submitting a product problem and/or an adverse event.
- O A healthcare professional submitting a product problem and/or adverse event report involving a tobacco product
- O A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving a tobacco product
- O A clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study.
- O 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.
- O 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

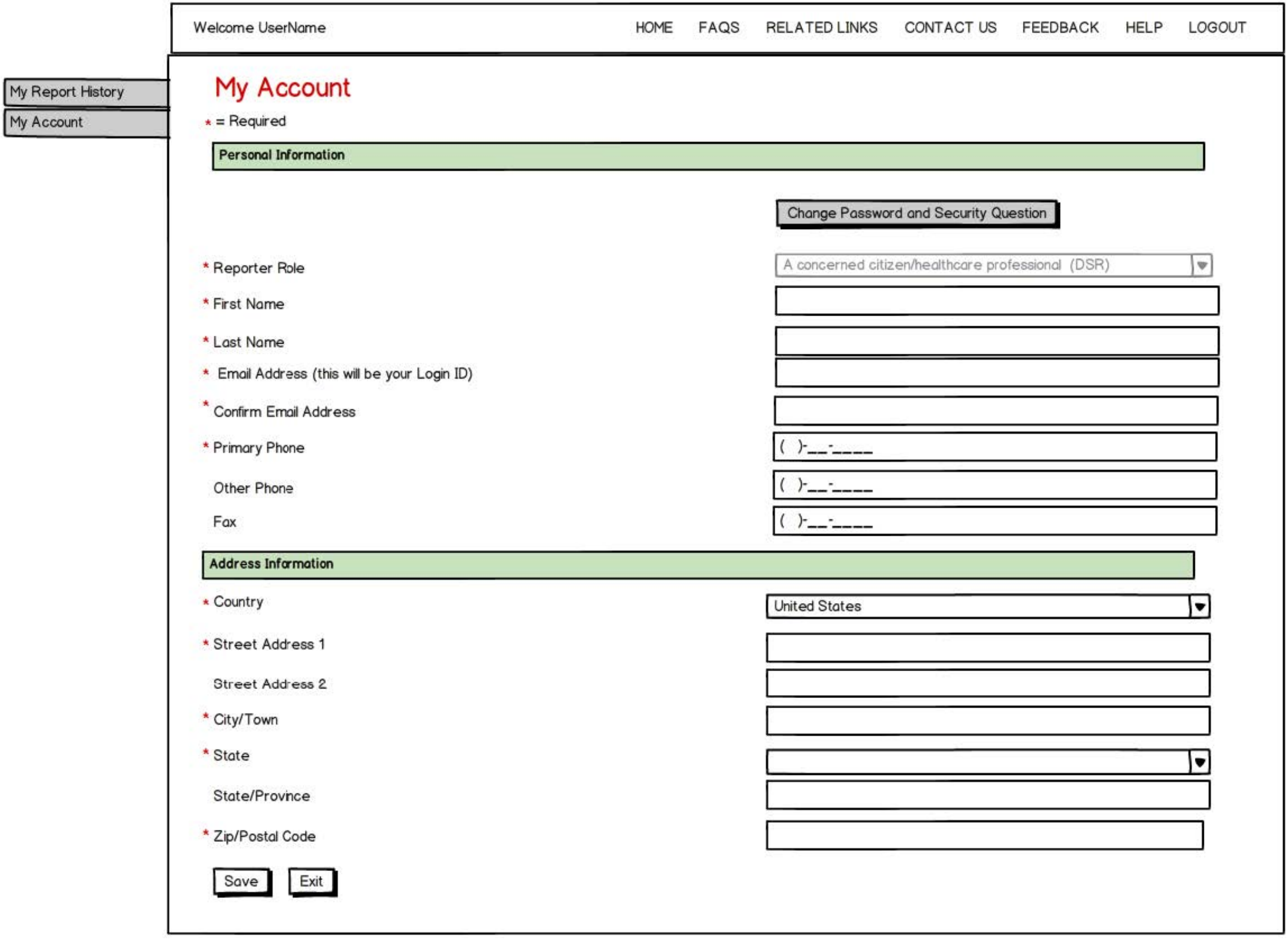
* Email Address (this will be your login ID)	
* Confirm Email Address	

Select a password:

- at least 8 characters long - at least one symbol/special character (Example: !, @, #, %, ^, &, *, _, -, .)
- with no blank spaces - 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
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

Begin Report 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.

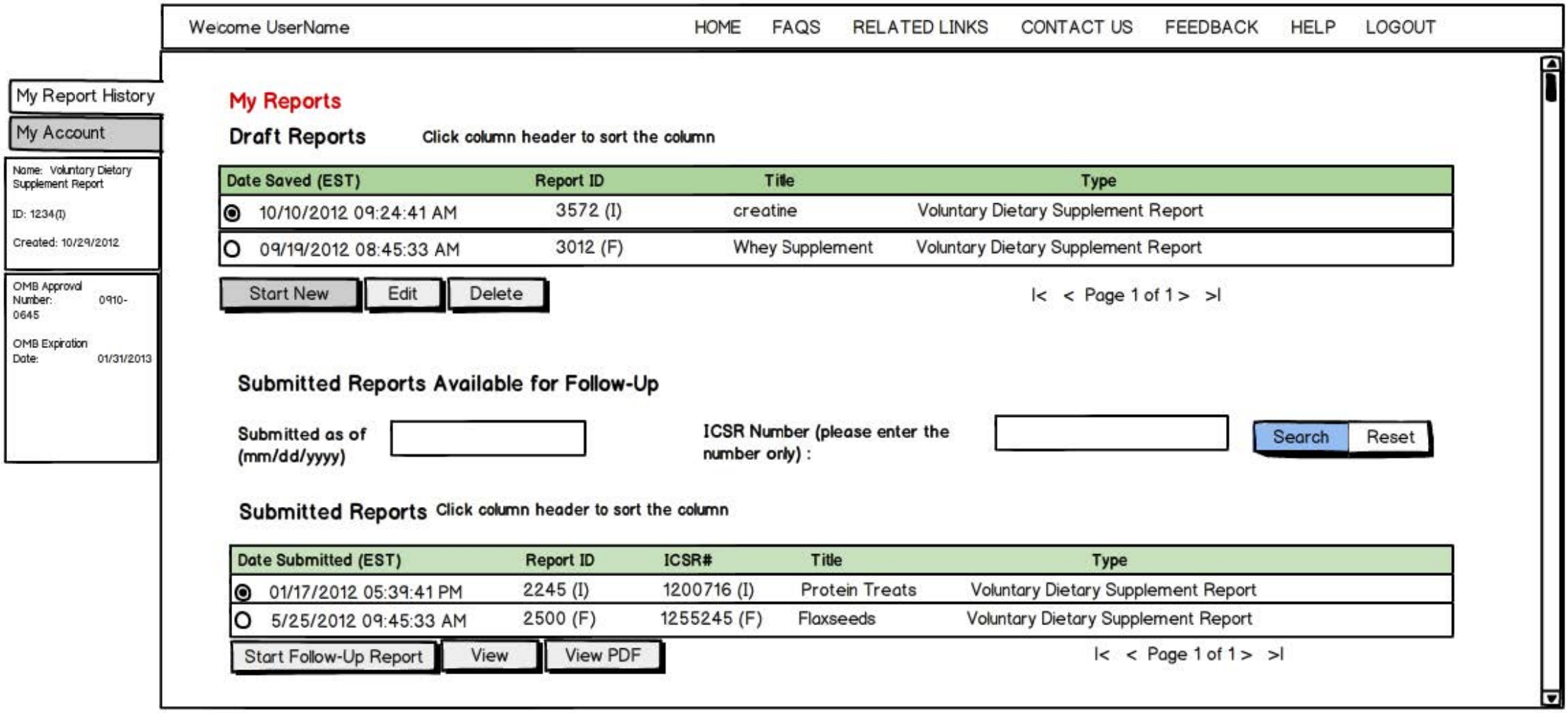
***Select the option that best describes what you want to do:**

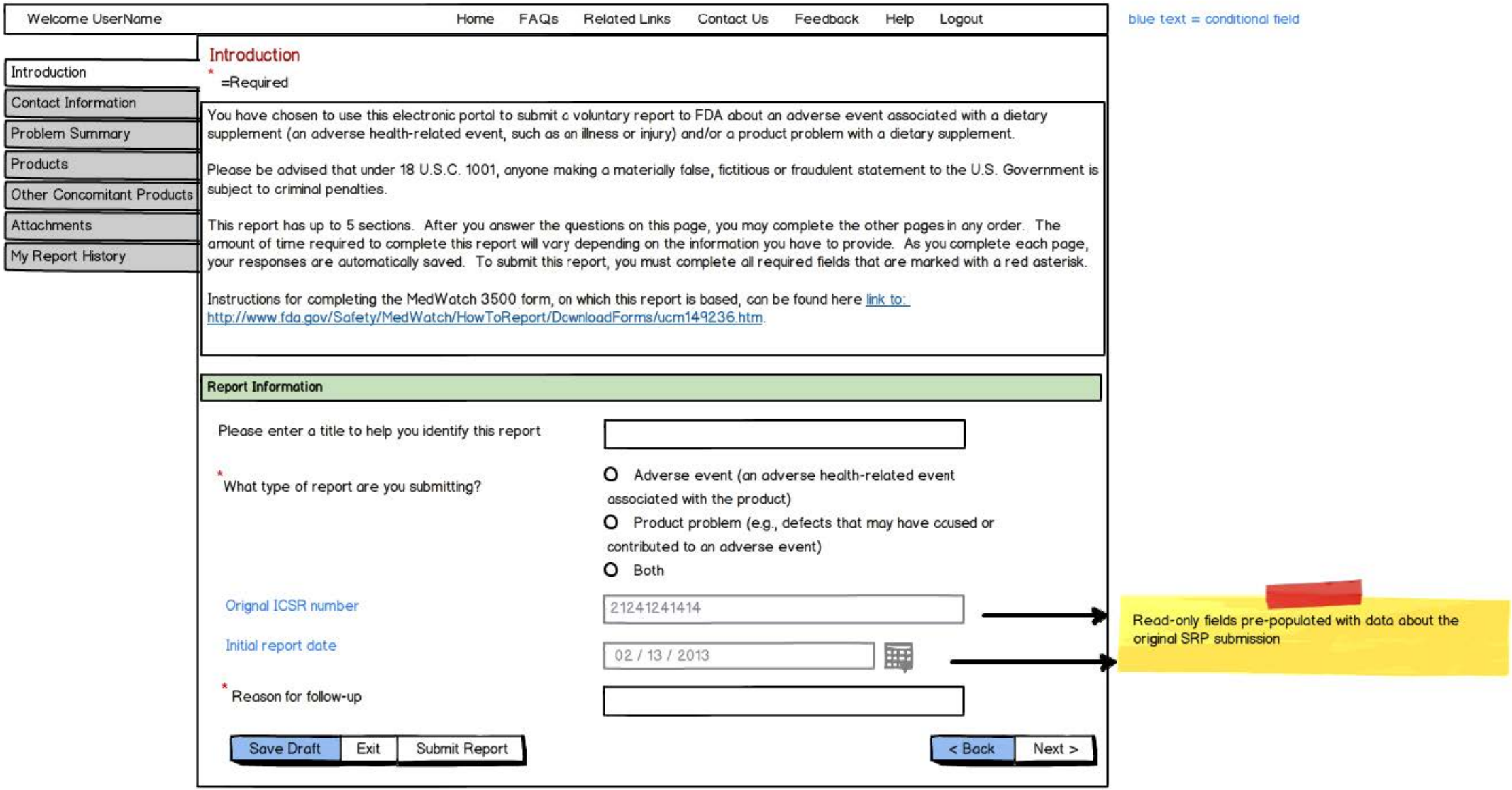
- (•) Start a new report
- ( ) Follow-up on a report previously submitted as a guest portal user
- ( ) Follow-up on a report previously submitted as a logged in user.
- ( ) None of the above

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

- ( ) A food facility or responsible party that manufactures, processes, packs, or holds foods 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 submitted a product problem and/or adverse event report involving pet food.
- ( ) A consumer or concerned citizen who is submitting a product problem and/or adverse event involving pet food.
- ( ) A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on a product problem and/or an adverse event.
- ( ) A healthcare professional submitting a product problem and/or adverse event report involving a tobacco product.
- ( ) A consumer or concerned citizen who is submiitting a product problem and/or adverse event report involving a tobacco product.
- ( ) A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.
- (•) A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness or injury associated with dietary supplement(s), or a dietary supplement manufacturer, packer, or distributor who is submitting a voluntary adverse event and/or product problem report.
- ( ) A clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study.
- ( ) None of these describe me.

[Begin Report] [Exit]


Welcome UserName
HOME
FAQS
RELATED LINKS
CONTACT US
FEEDBACK
HELP
LOGOUT
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
10/10/2012 09:24:41 AM
3572 (I)
creatine
Voluntary Dietary Supplement Report
09/19/2012 08:45:33 AM
3012 (F)
Whey Supplement
Voluntary 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
Voluntary Dietary Supplement Report
5/25/2012 09:45:33 AM
2500 (F)
1255245 (F)
Flaxseeds
Voluntary Dietary Supplement Report
Start Follow-Up Report
View
View PDF
I< < Page 1 of 1 > >I


Welcome UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Other Concomitant Products
Attachments
My Report History
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.
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
Orignal ICSR number
21241241414
Initial report date
02 / 13 / 2013
* Reason for follow-up
Read-only fields pre-populated with data about the original SRP submission
Save Draft
Exit
Submit Report
< Back
Next >

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

blue text = conditional field

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

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.

Report Information

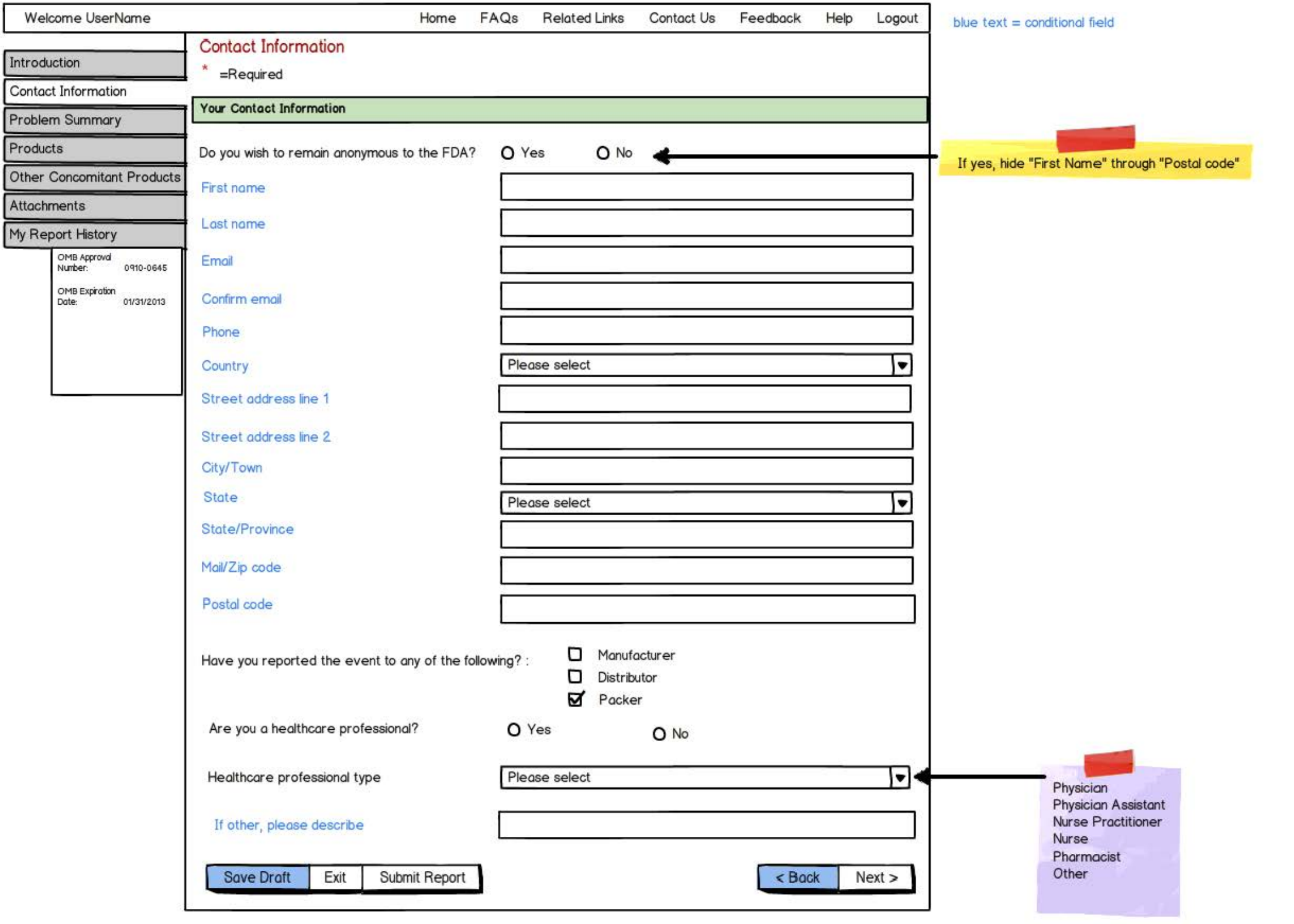
Please enter a title to help you identify this report. [ ]

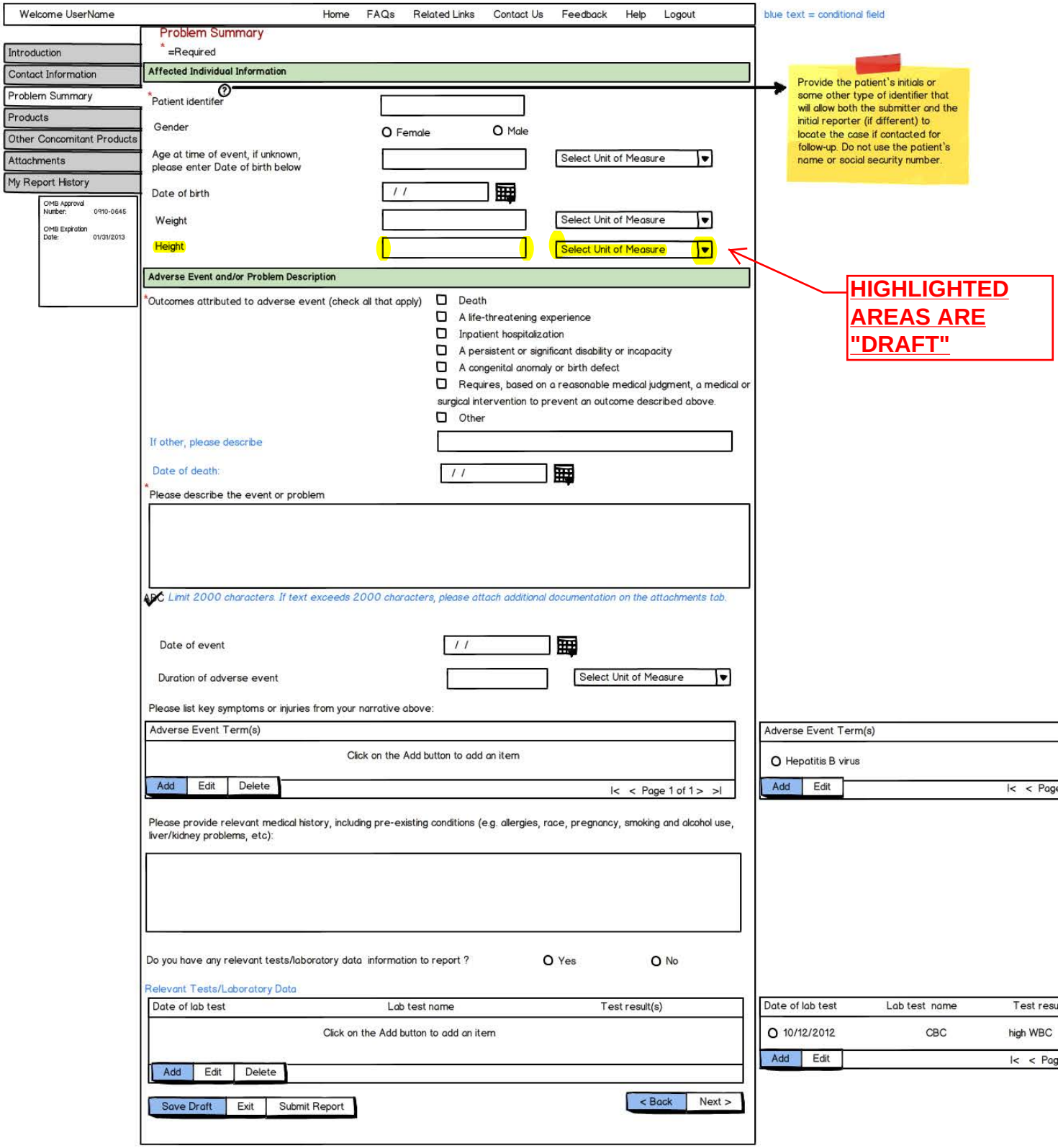
* What type of report are you submitting?

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

Save Draft | Exit | Submit Report

< Back | Next >


Welcome UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Other Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
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
Physician
Physician Assistant
Nurse Practitioner
Nurse
Pharmacist
Other
If other, please describe
Save Draft
Exit
Submit Report
< Back
Next >


Welcome UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Other 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 AREAS ARE "DRAFT"
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
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 test
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."

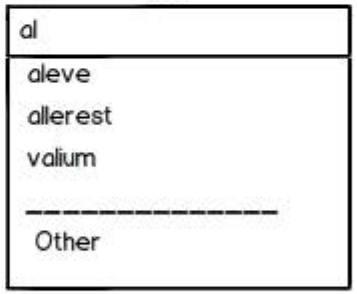
* Adverse event term — Type to search and select

If other, please describe

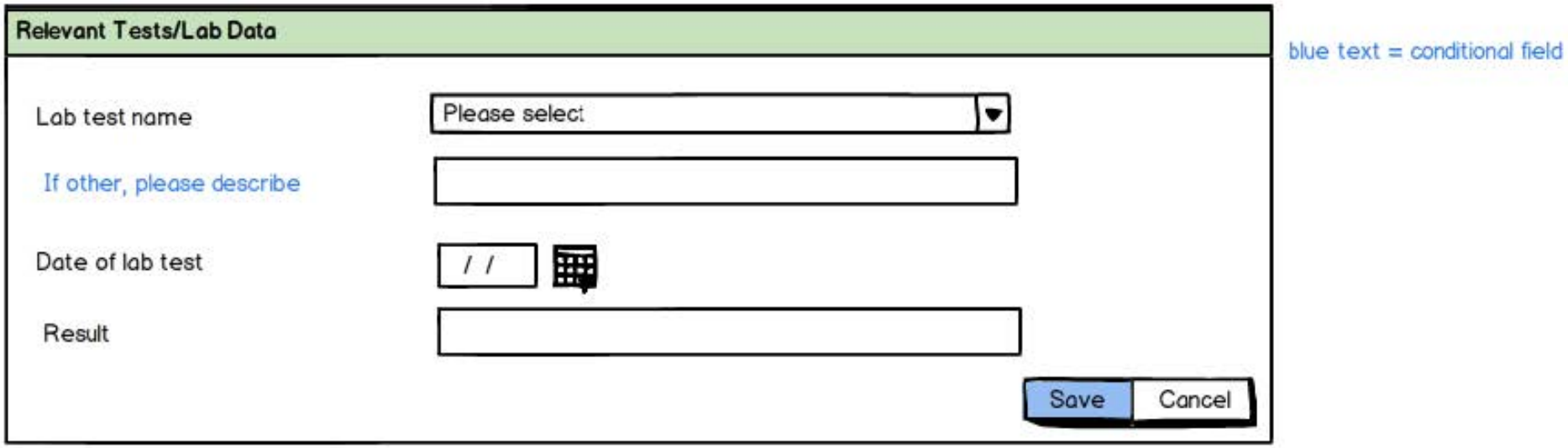
Save | Cancel

blue text = conditional field

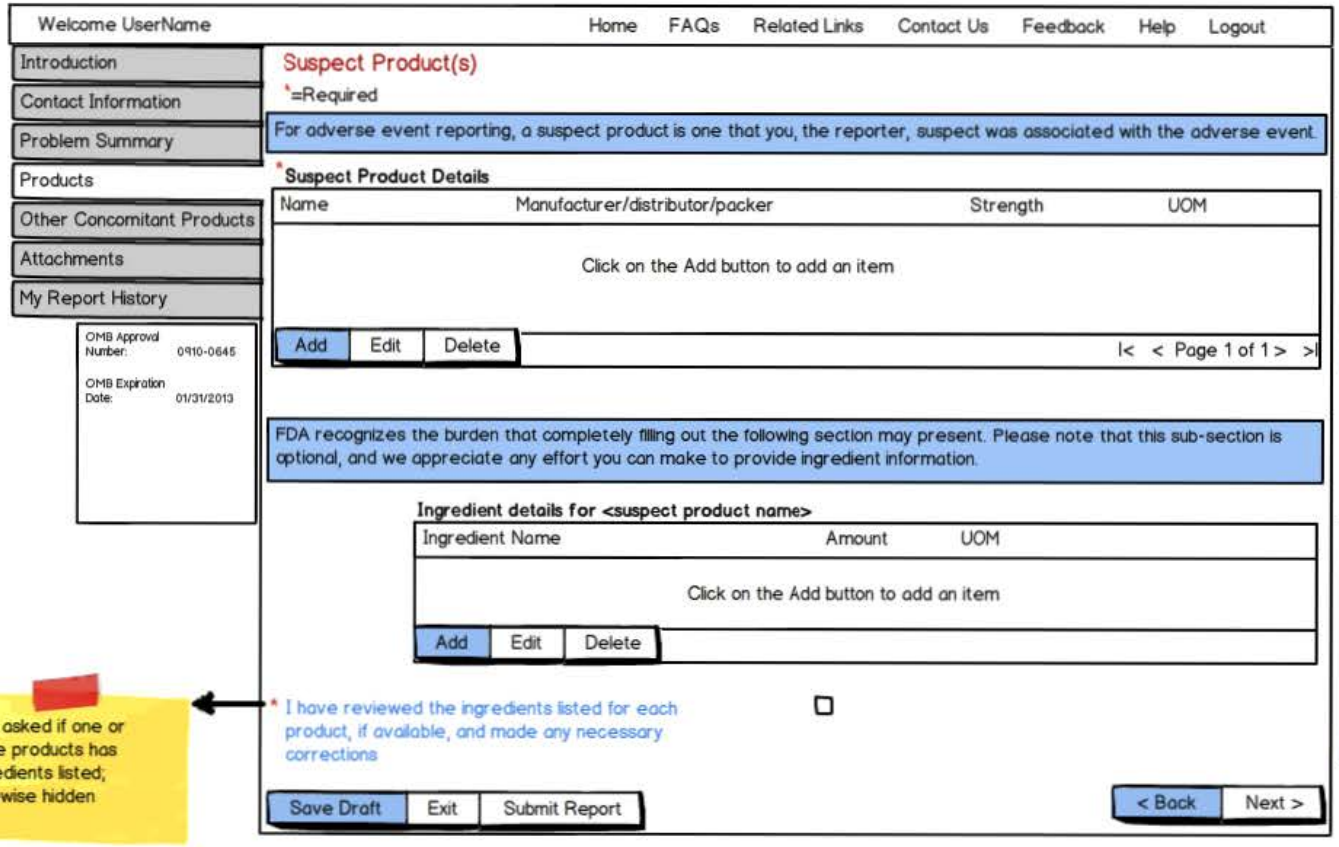
Type ahead control with "Other' option always available



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



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

blue text = conditional field

Grid view after products are added

Name	Manufacturer/distributor/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 = 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: 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 name of product

Product manufacturer, packer, 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

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

Was product returned to manufacturer? O Yes O No O Unknown

Date product was returned to manufacturer: / /

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: Select unit of measure

Frequency of consumption: Select unit of measure

Amount consumed per serving: Select unit of measure

Administration route: Please select

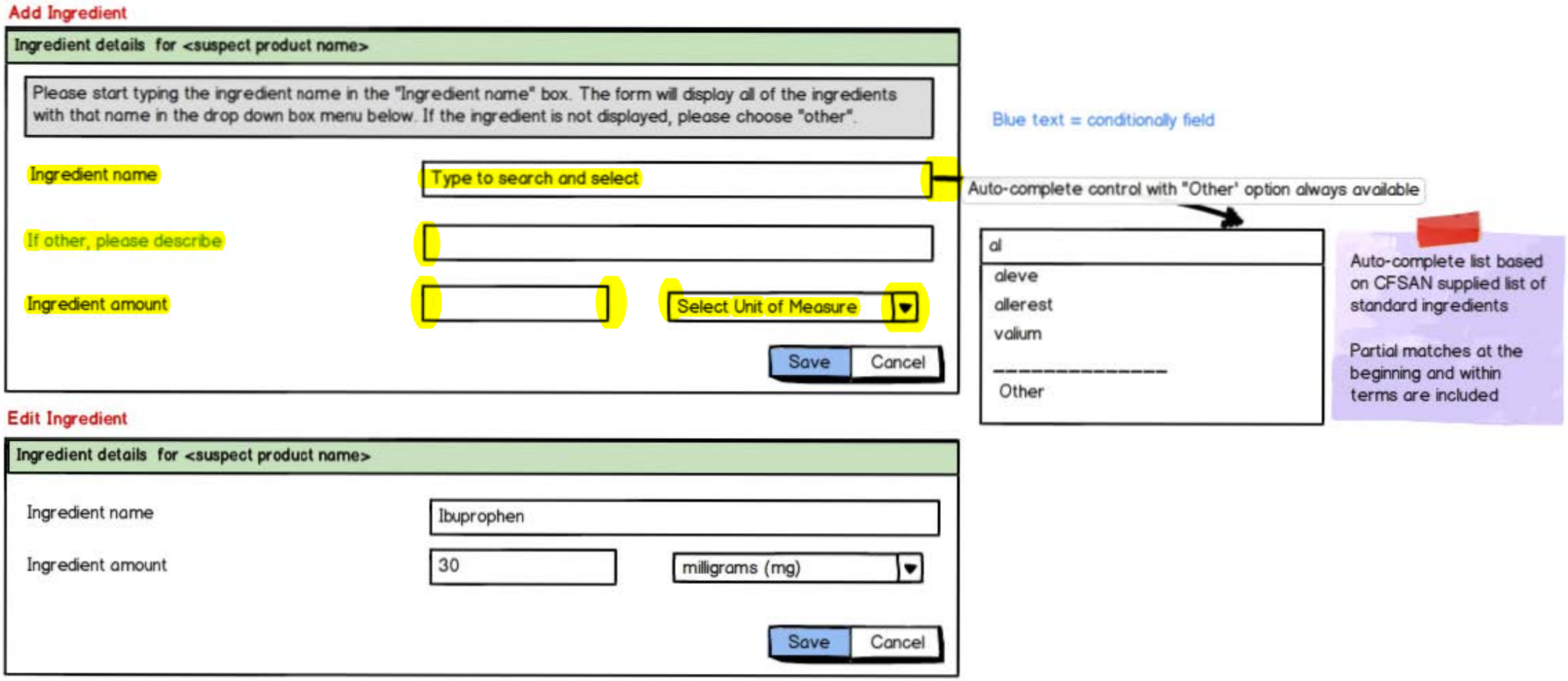
Did the event stop when product use stopped or the amount consumed was reduced? O Yes O No O Unknown O Not Applicable

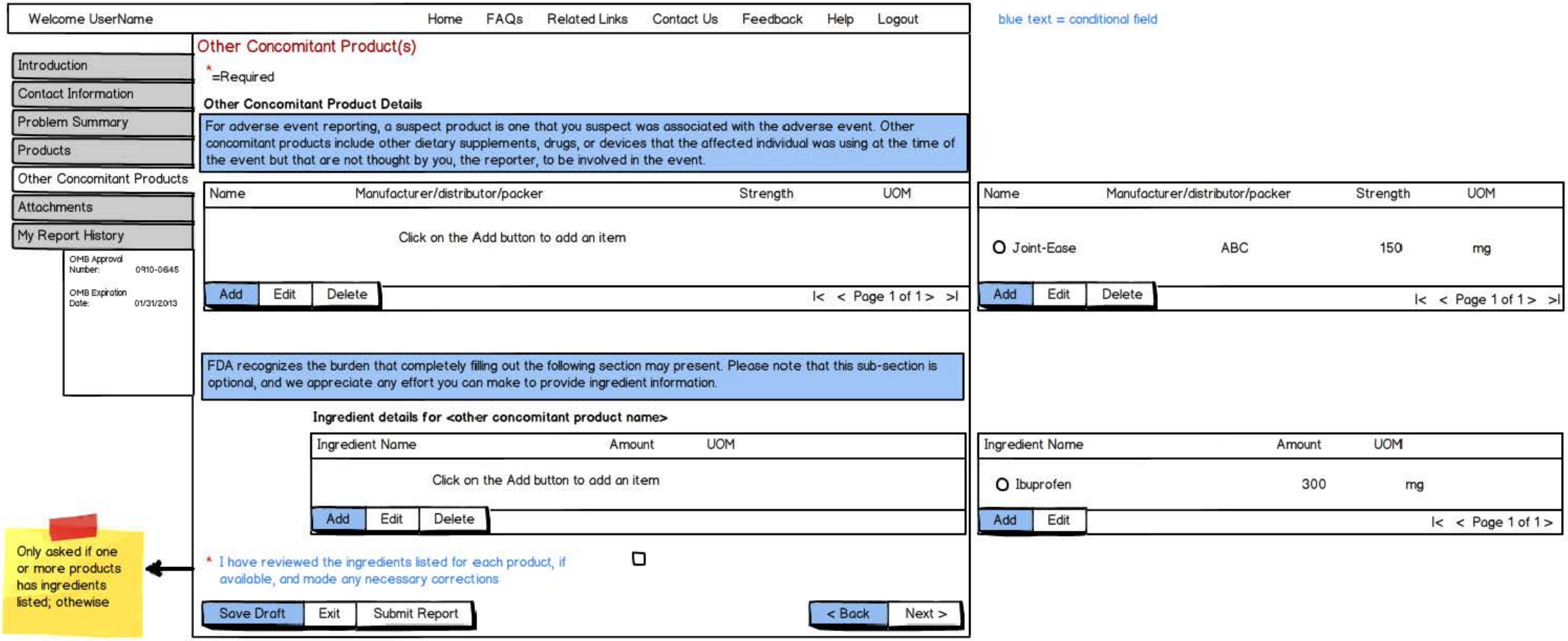
Did the event reoccur when product use resumed? O Yes O No O Unknown O Not Applicable

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 UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
blue text = conditional field
Introduction
Contact Information
Problem Summary
Products
Other Concomitant Products
Attachments
My Report History
OMB Approval Number: 0910-0645
OMB Expiration Date: 01/31/2013
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
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 <other 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 >
Only asked if one or more products has ingredients listed; othewise
* I have reviewed the ingredients listed for each product, if available, and made any necessary corrections
Save Draft
Exit
Submit Report
< Back
Next >

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:

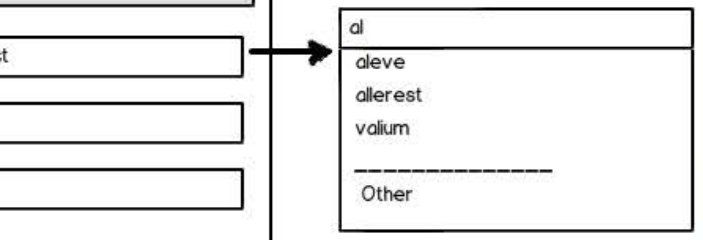
Diagnosis or reason for use (indication):

ABC

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

Lot number:

Expiration/use-by date: / /



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

Partial matches at the beginning and within terms are included

UPC
Other

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

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

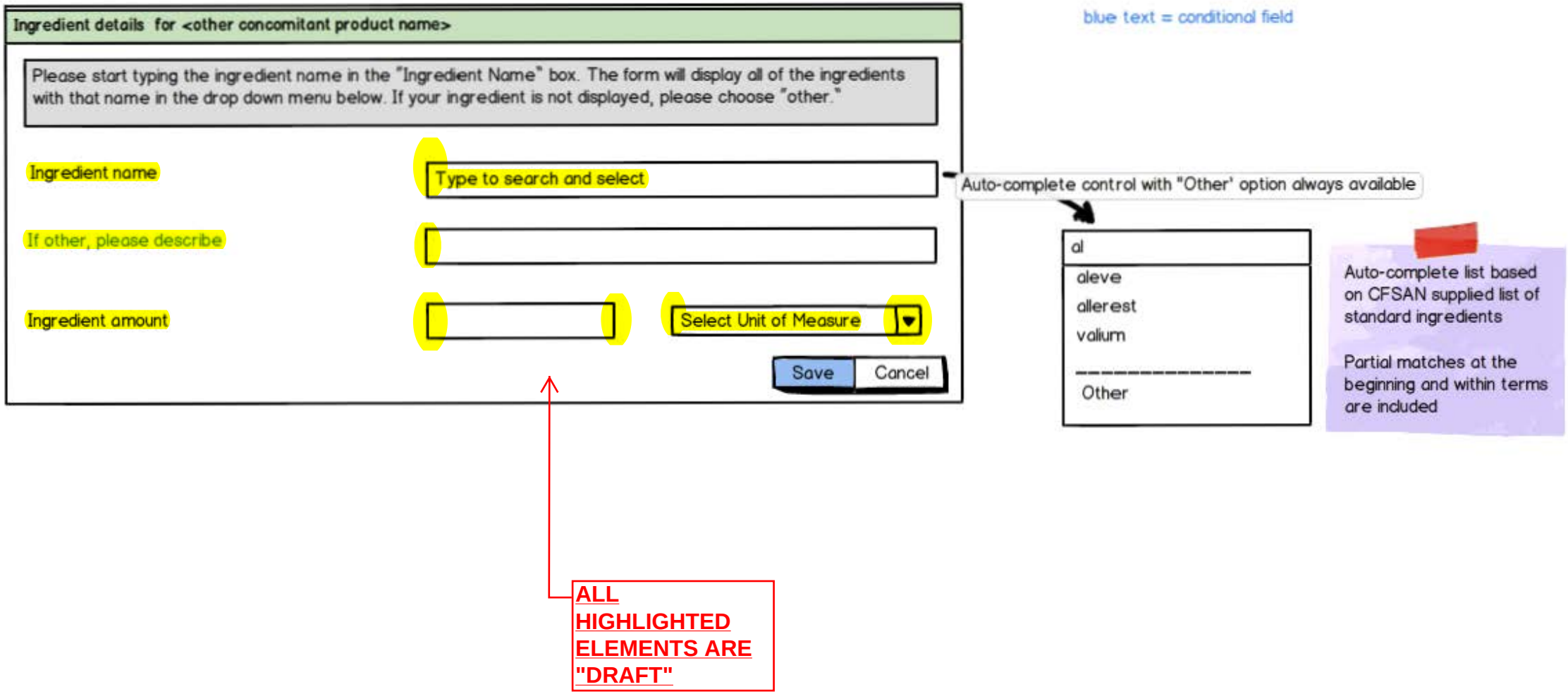
Amount consumed per serving: Select unit of measure

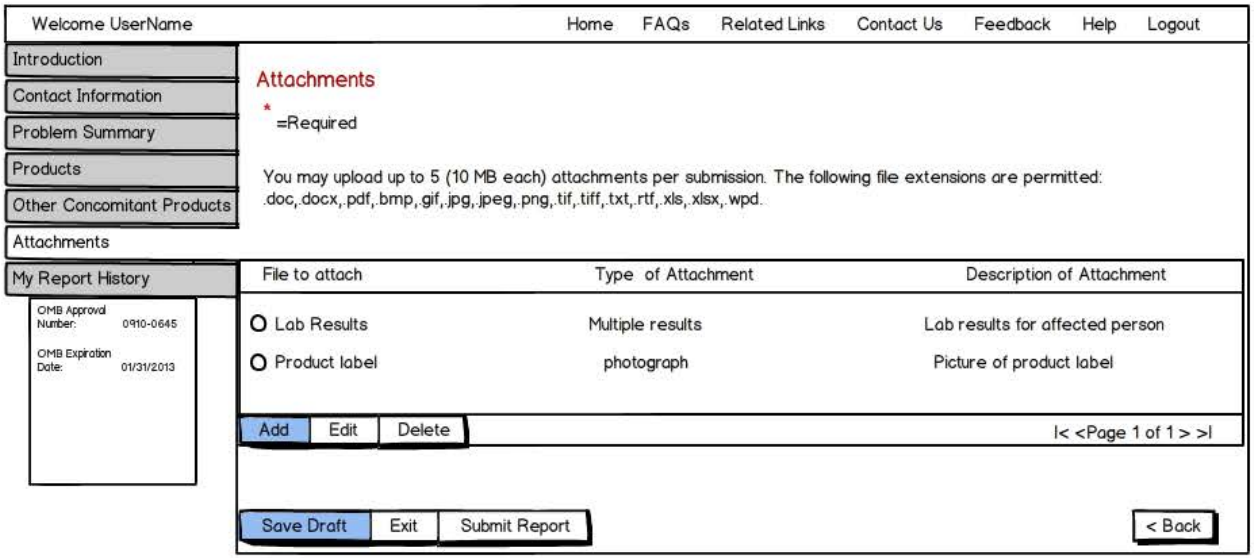
Administration route: Please select

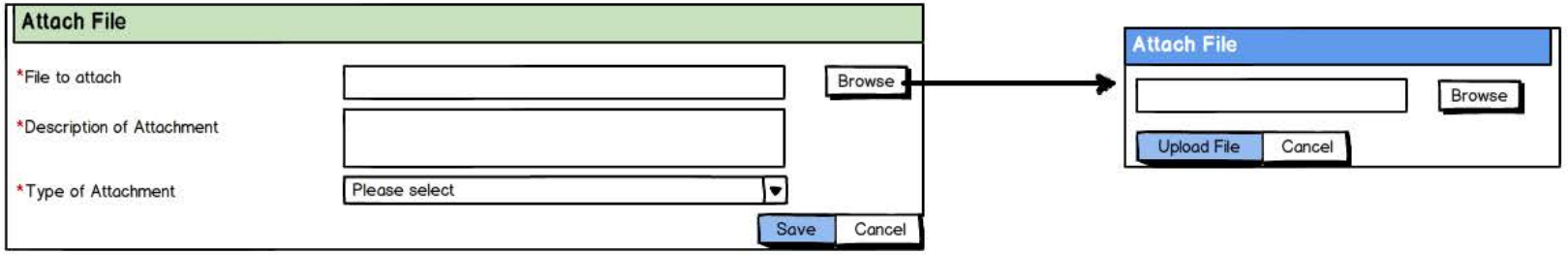
Please provide any notes describing the product's usage:

ABC

Save Cancel

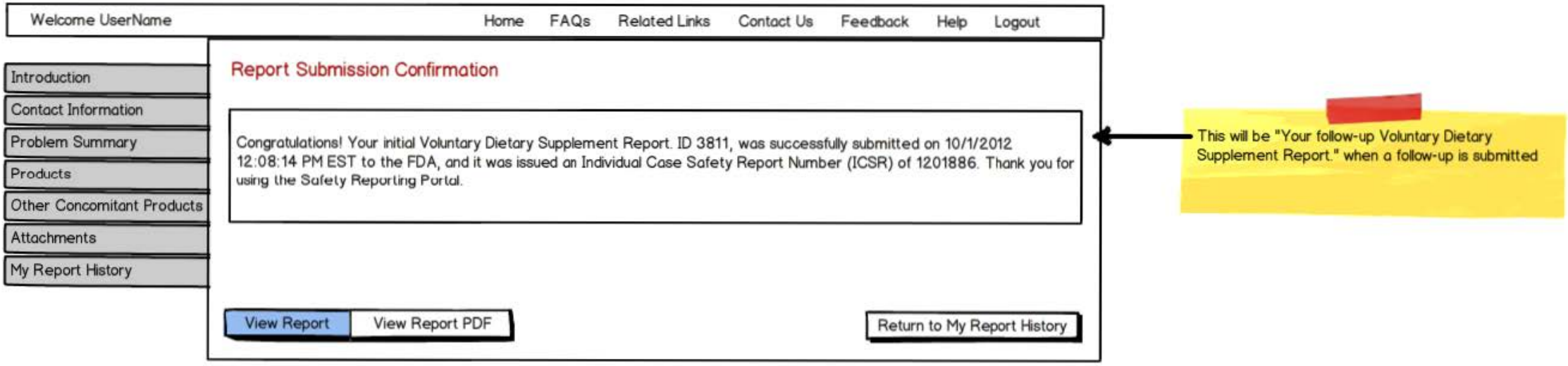

Ingredient details for <other concomitant product name>
Please start typing the ingredient name in the "Ingredient Name" box. The form will display all of the ingredients with that name in the drop down menu below. If your ingredient is not displayed, please choose "other."
Ingredient name
Type to search 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
ALL HIGHLIGHTED ELEMENTS ARE "DRAFT"


Welcome UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
Introduction
Contact Information
Problem Summary
Products
Other 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

*


Welcome UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
Introduction
Contact Information
Problem Summary
Products
Other 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 UserName
Home
FAQs
Related Links
Contact Us
Feedback
Help
Logout
Introduction
Contact Information
Problem Summary
Products
Other Concomitant Products
Attachments
My Report History
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.
View Report
View Report PDF
Return to My Report History
This will be "Your follow-up Voluntary Dietary Supplement Report." when a follow-up is submitted