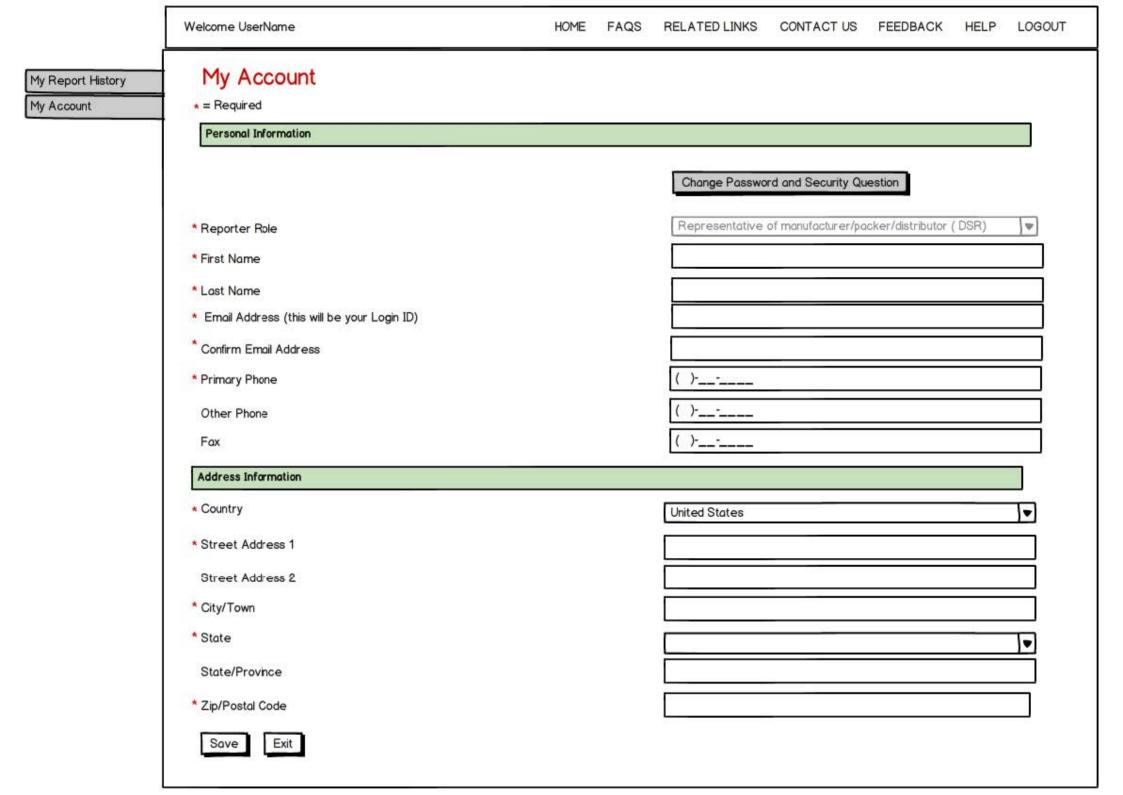
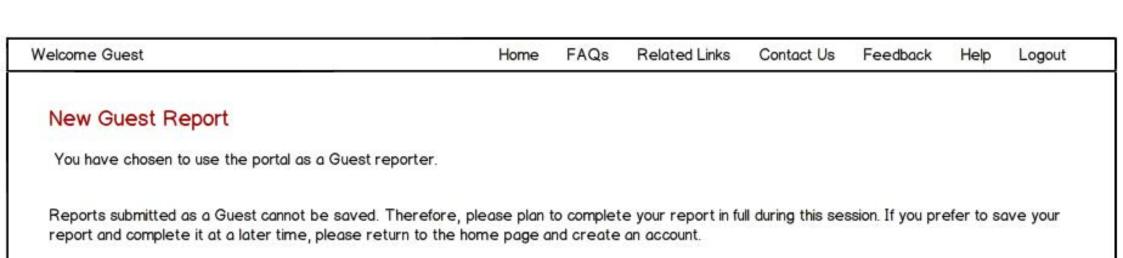
For other issues, find out where to submit your report.

Learn more about mandatory and voluntary reporting

	HOME	FAQS	RELATED LINKS	CONTACT US	FEEDBACK	HELP	LOGOUT
Account Registration *=Required							
* Which of the following best describes you?							
O A food facility or responsible party that manu	factures,	processes	s, packs, or holds food	who is submitting o	reportable food	i report.	
O A federal, state, or local public health official	who is sub	omitting a r	eportable food report	involving human an	d/or animal food		
O A veterinarian or veterinary staff member w	ho is subr	nitting a pr	oduct problem and/or	adverse event re	port involving pe	t food	
O A consumer or concerned citizen who is subn	nitting a p	roduct pro	blem and/or adverse	event report involv	ring pet food		
O A marketing authorization holder (manufactur	er) for an	animal dru	ug who is submitting a p	product problem ar	id/or an adverse	e event.	
O A healthcare professional submitting a produc	- CAN-COLD						
A consumer or concerned citizen who is subr A clinical trial primary investigator or research				and the second second			
A dietary supplement manufacturer, packer, or a dietary supplement manufacturer, packer, or a dietary supplement manufacturer.				2/ 2			
O A consumer, concerned citizen, or healthcare	e profess	ional who is	s submitting a report a	bout an illness or in	jury associated i	with dietar	y supplement(s),
or a dietary supplement manufacturer, packer, o	r distribut	or who is a	submitting a voluntary of	adverse event and	/or product prob	olem repo	rt.
O None of these describe me.							
Your Contact Information		OV.					24
* First Name							
* Lost Name							
* Primary Phone							i
Other Phone							
Fcx				- <u> </u>			
* Country		Plea	se Select				•
* Street Address Line 1							
Street Address Line 2		F					5
*		<u> </u>	-				<u>, </u>
City/Town							
* State		Pleas	se Select				•
State/Province							ĭ
* ZIP/Postal Code							
		7	·				
Your Login Credentials							
* Email Address (this will be your login ID)				55.73			1
* Confirm Email Address							
Select a password:							
· at least 8 characters long	- at l	east one s	symbol/special characte	er (Example: !. @.	#. %. ^. &. *.)	
· with no blank spaces			t or end with a number			10100	
with the blank spaces	- 404	es not star	t or end with a number	FI			42
* Pcssword							
* Confirm Password							
* Security Question							
* Security Question Answer				-			
Submit Exit							





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

- Start a new report
- O Follow-up on a report previously submitted as a guest portal user
- O Follow-up on a report previously submitted as a logged in user.
- O 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:

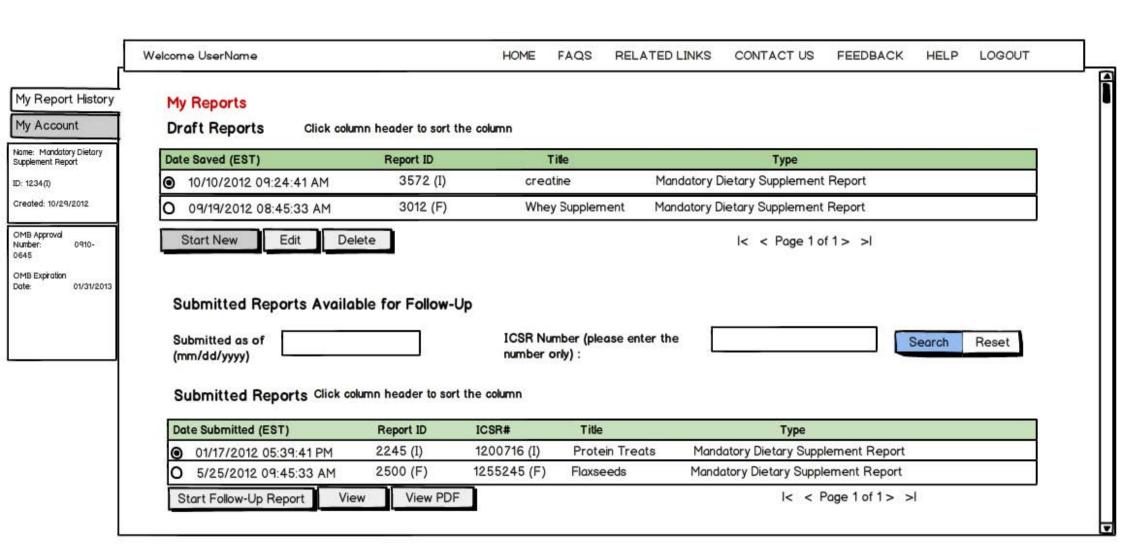
- Start a new report
- Follow-up on a report previously submitted as a guest portal user
- O Follow-up on a report previously submitted as a logged in user.
- O None of the above

*Which of the following best describes you?

- O A food facility or responsible party that manufactures, processes, packs, or holds foods 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 submitted 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 involving pet food.
- O A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on 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.
- A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.
- O A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness or injury associated with dietary
- or a dietary supplement manufacturer, packer, or distributor who is submitting a voluntary adverse event and/or product problem report.
- O 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



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Introduction

=Requ

Contact Information

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Concomitant Products

Attachments

My Report History

OMB Approval

pprova r 0910-0645

OMB Expiration

a. 0410-00

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. Serious adverse event (a serious adverse health-related event) What type of report are you submitting? 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? ☐ Consumer (check all that apply) Friend or Relative Distributor Health Professional □ Lawyer Social Media ☐ Other If other, please describe < Back Next > Save Draft Exit Submit Report

Tee Co	 	conditi	market and	E-11

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

Introduction

Introduction

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Contact Information Problem Summary

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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.

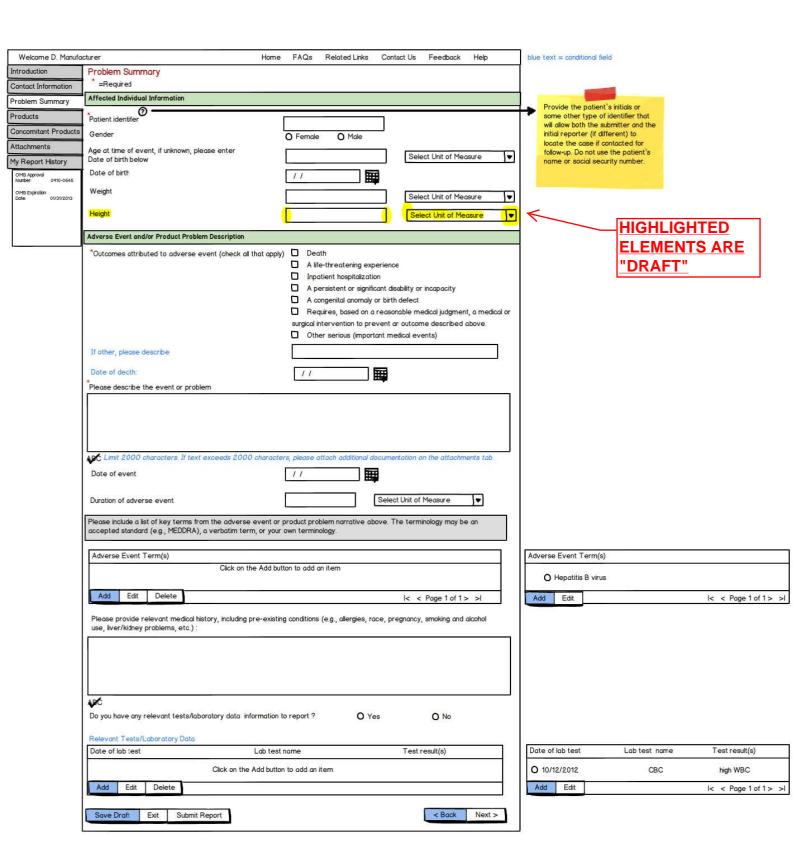
FDA has made available, for those who choose to use it, this method of electronic submission for mandatory serious adverse event reports about a dietary supplement. FDA will accept reports filed via this portal to satisfy firms' statutory reporting duty under section 761 of the FD&C Act and intends to 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.

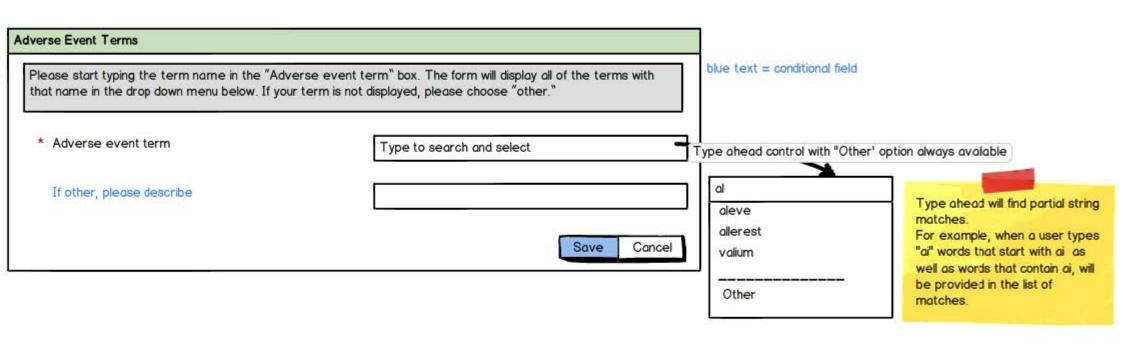
lease enter a title to help you identify this report. onsider using your firm's internal case tracking number or simplified recordkeeping.	
What type of report are you submitting?	 O Serious adverse event (a serious adverse health-related event associated with the product) O Serious adverse event and product problem (e.g., defects that make caused or contributed to a serious adverse event)
Enter the date you received the initial report:	1.1
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	
Orignal ICSR number	2354363463
Initial report date	03/ 01/2013
Reason for follow-up	

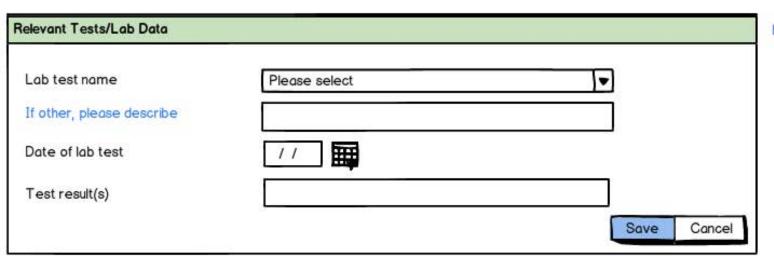
Read-only fields pre-populated with the original SRP report submission information

blue text = conditional field

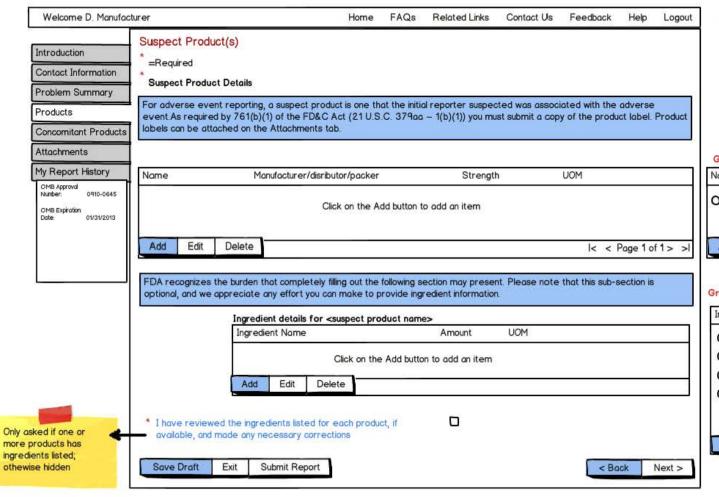
Welcome D. Manufa	cturer	Home FAQs Related Links Contact Us Feedback	Help blue text = conditional field
Introduction	Contact Information		
Contact Information	*=Required	n-2	
Problem Summary	Manufacturer, Packer, or Distributor Site Informat My account address is the same as the manufa	The state of the s	This field is shown only for account holders and hidden for guests.
Products Concomitant Products	*Organization name		If "Yes", fields from "Country" through "Postal Code" will be populated and
Attachments	*Organization type	Manufacturer	the rest of the fields are displayed empty and editable. If "No", all fields are displayed empty and editable.
My Report History	•	□ Packer □ Distributor	For Guests:
OMB Approval Number: 0910-0645	Take the control of t	Other	Show all fields from 'Organization Name" through 'Postal Code" empty and editable.
OMB Expiration Date: 01/31/2013	If other, please describe		
	Food facility registration number *Country	United States ▼	
	*Street address 1	omed dured	
	Street address 2		
	*City/Town		
	State		
	State/Province	[-	
	The state of the s		
	*Mail/ZIP code Postal code		
	1 0000		
	Site Point of Contact Information		
	Please provide the contact information of some	one at the manufacturer's, packer's, or distributor's organization in the ev	vent
	that FDA follow-up is necessary		
	* I am the point of contact for the facility listed a	bove O Yes O No	Only for guest reporters:
	First name		If the submitter is NOT the Site Point of Contact, then show "First Name" through "Fax" in this section, display Report Submitter Contact Information
	Last name		section with a full contact information block for the report submitter before the Initial Reporter.
	Job title		If the submitter IS the Site Point of Contact, then populate "First Name"
	Email		through "Fax" in this section; Report Submitter Contact Information section is hidden.
	Confirm email		Only for account holders:
	Primary phone		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
	Other phone		section is hidden.
	Fox		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.
	Report Submitter Contact Information		
	Please provide contact information for you, the p	erson who is filing out this report	
		4	
	(First name)		
	(Last name)		
	(Emoil)	<u></u>	
	Confirm email	<u></u>	
	Phone	<u></u>	
	Fax		ALL
	Country	Please select	<u> </u>
	Street address line 1	<u></u>	HIGHTLIGHTED
	(Street address line 2) (City/Town)	<u> </u>	ELEMENTS ARE
	State	Please select	"DRAFT"
	State/Province		DRAFI
	Mail/Zip code		
	Postal code	ĺ i	
	Tamala -	<u> </u>	
	Initial Reporter		
		itial Reporter. The initial reporter is the person who notified you, the . In order to provide a complete report, you must provide an identifier fo	or the
	initial reporter or state that they wish to remain guidance.	anonymous. Acceptable identifiers are explained in link to: section 13 of t	the link to:
			http://www.fdo.gov/food/quidancecompliancer-egulatoryin formation/guidance documents/dietarysupplements/ucm1 71383 htm.
	Did the inital reporter indicate that they also r to the FDA?	eported the event O Yes O No O Unknown	
	*	100 LLC 2 1000	If yes, hide "Salutation" through "Postal code"
	Does the initial reporter wish to remain anony	mous to the FDA? O Yes O No	
	Salutation	Please select ▼	<u> </u>
	First name		Mr. Mrs.
	Last name		Ms. Miss
	Email		Dr. Rev.
	Confirm email		i ••••
	Phone		i
	Country	Please select	<u> </u>
	Street address line 1		i
	Street address line 2		i
	City/Town		i
	State	Please select	<u> </u>
	State/Province]
	Mail/Zip code		
	Postal code		
	Was the initial reporter a healthcare professi	onal? O Yes O No O Unknown	_
	Healthcare professional type	Please select	Physician
	If other, please describe		Physicion Assistant Nurse Practitioner
	- House has not a required with the control of the	-	Nurse Pharmacist
	Save Draft Exit Submit Report	< Back Next :	Other







blue text = conditional field



blue text = conditional field

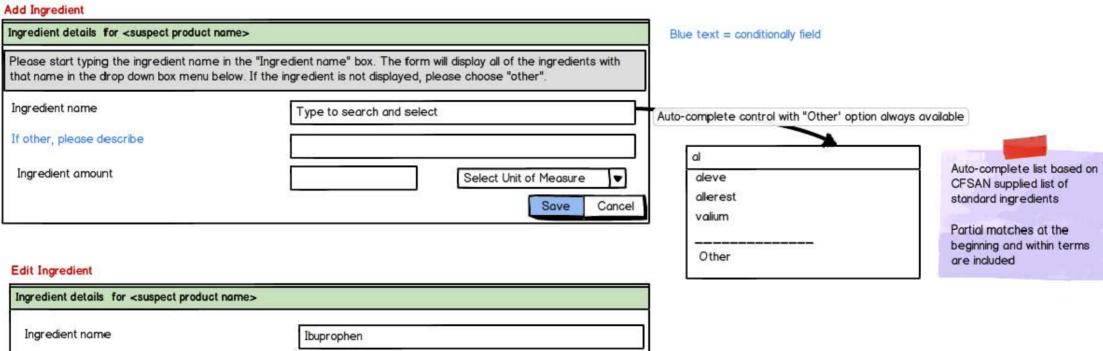
Grid view after products are added

Name Manufactu		rer/disributor/packer	Strength	UOM		
O Joint-Ease ABC		ABC	150)	mg	
Add	Edit	Delete			l< < Page	1 of 1 > >l

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

Ingredie	nt Name	Amount	UOM
O Ibup	rofen	300	mg
O Vita	min D	200	g
O Calc	sium	45	mg
O Vita	min B12	10	ug
	T = 1		
Add	Edit		<pre>I< < Page 1 of 1 ></pre>

Ingredient amount



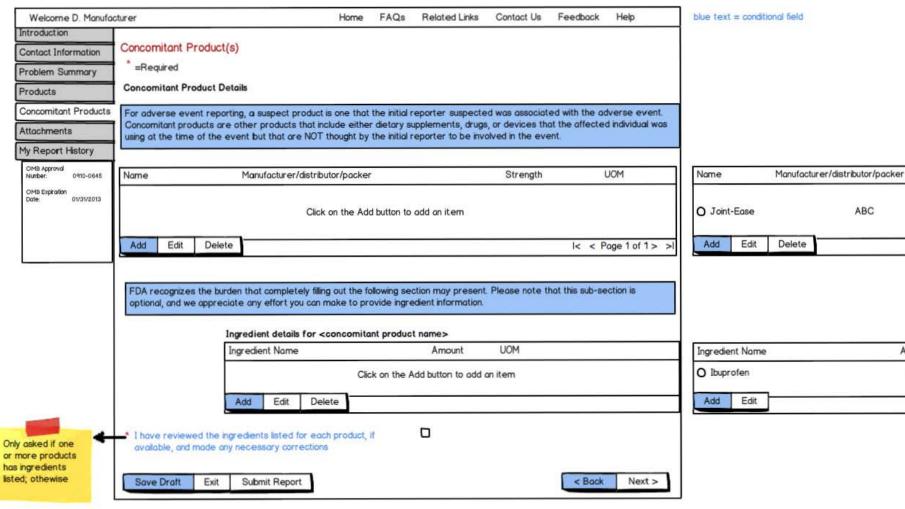
Save

milligrams (mg)

.

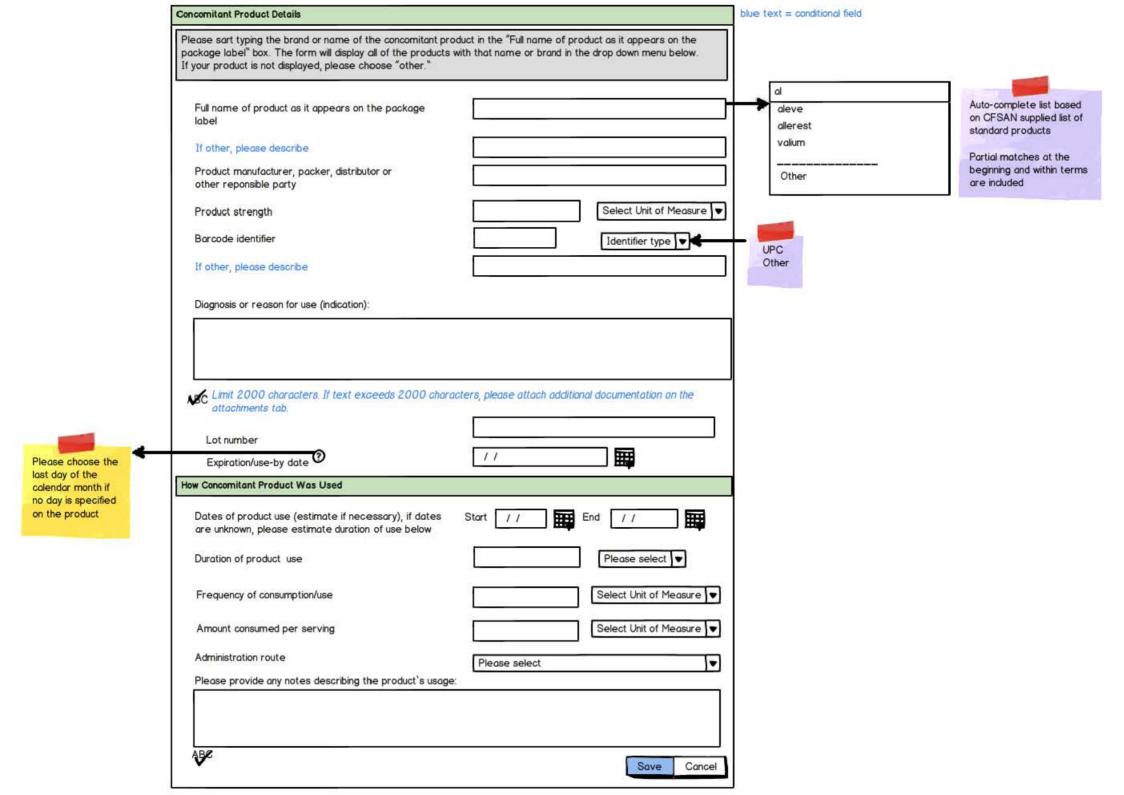
Cancel

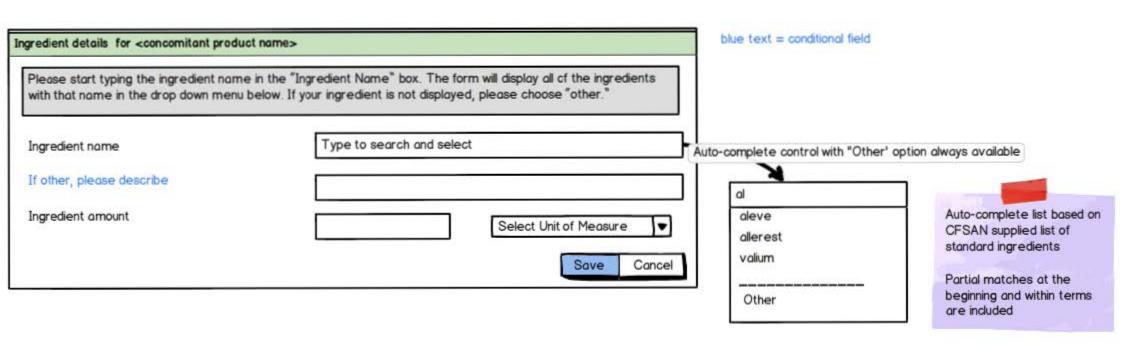
30

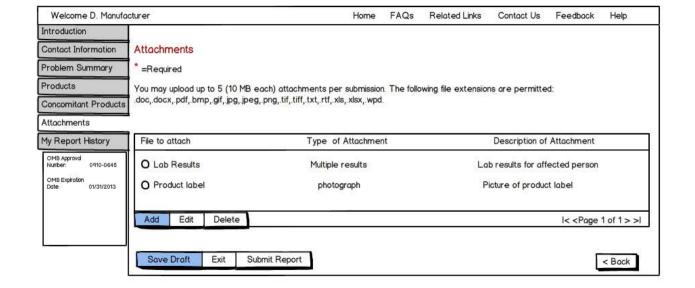


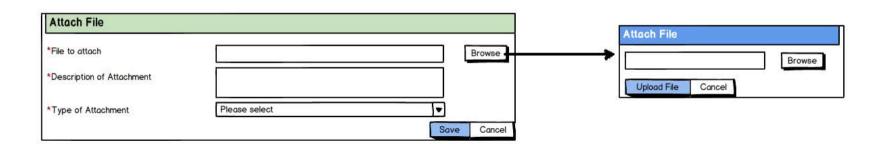
Name Manufactu		Manufactu	rer/distributor/packer	Strength	UOM	
O Joint	-Ease		ABC	150	mg	
Add	Edit	Delete		k	< Page 1 of 1 > >l	

Ingredie	nt Name	Amount	UOM	
O Ibupr	ofen	300	mg	
Add	Edit		I< < P	age 1 of 1 >









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