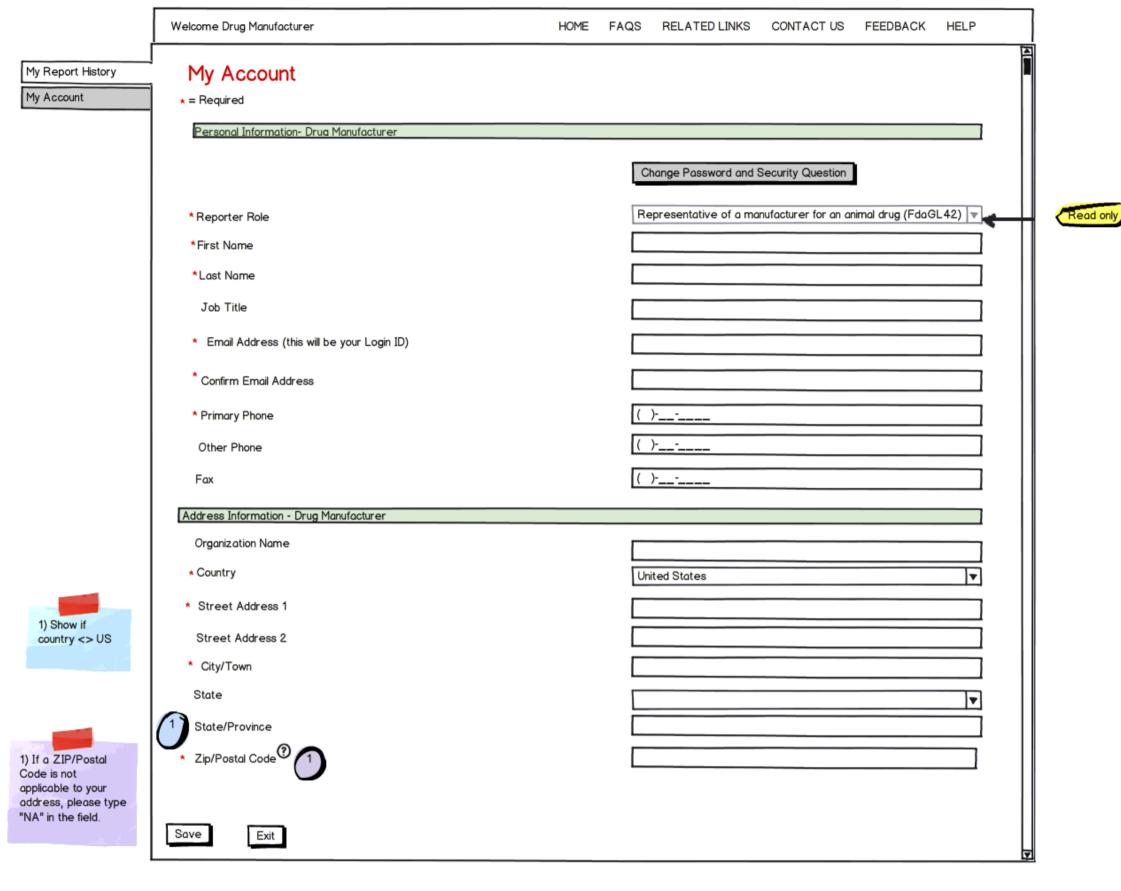
1. Login Email Not ready to create an account but would like to submit a report? Password Forgot your password? Remember me 2. Report As Guest Not ready to create an account but would like to submit a report? You can do that here. Report as Guest Create	DRAFT		Begin Reporting I	Here
Not ready to create an account but would like to submit a report? Password Or Forgot your password? You can do that here. Remember me Not ready to create an account but would like to submit a report? Password You can do that here.		•	2. Report As Guest	Account Benefits
Password Or Forgot your password? Remember me Submit a report? View submissions Fast data entry		Email		
☐ Remember me		Password		 View submissions
		Forgot your password?	You can do that here.	
Login Create		☐ Remember me		
		Login	Report as Guest	Create

HOME F	AQS	RELATED LINKS	CONTACT US	FEEDBACK	HELP	LOGOUT
Account Registration *=Required					D	RAFT
∗Which of the following best describes you?						
O A food Facility or responsible party that manufactures, pro	ocesses,	packs, or holds food	who is submitting	reportable foo	d report	
O A federal, state, or local public health official who is submi	tting a rep	oortable food report	involving human an	d/or animal food	ı	
O A veterinarian or vetrinary staff member who is submittin	g a produ	ct problem and/or a	dverse event repo	ort involving pet	food	
O A consumer or concerned citizen who is submitting a product	luct proble	em and/or adverse	event report involv	ing pet food		
O A marketing authorization holder (manufacturer) for an an						port
O A Clinical trial primary investigator or researcher who nee				-		
A healthcare professional submitting a product problem a						
O A consumer or concerned citizen who is submitting a prod	luct proble	em and/or health-re	lated problem repo	ort involving a to	bacco pro	duct
O None of the above describes me						
Your Contact Information						
First Name						
*First Name						
*Last Name						
*Country	Please	Select				V
*Phone				_		
*Street Address Line 1						
Street Address Line 2						
*City/Town	\vdash					
*State	Please	Select				
*State/Province	- Tease					
*ZIP/Postal Code						
<next "which="" 4="" answers="" best="" describes="" following="" for="" healthcare="" if="" of="" only="" professional="" prompts="" question="" shown="" the="" user="" you?"=""> Organization</next>						
Title						
Healthcare professional type	Please					▼
Describe Other	<show< td=""><td>only if the Healthca</td><td>re Professional Ty</td><td>pe is Other></td><td></td><td></td></show<>	only if the Healthca	re Professional Ty	pe is Other>		
Your Login Credentials						
*Email Address (this will be yur login ID)						
*Confirm Email Address	<u> </u>					
Select a password: • at least 8 characters long - at least	st one syn	nbol/special characte	er (Example: !, @,	#, %, ^, &, *, _	_, -, .)	
*Decembed						
*Password						
*Confirm Password						
*Security Question						
*Security Question Answer						
Submit Exit <submit: account="" and="" changes;="" create="" email="" save="" send="" td="" to="" use<="" user=""><td>er to valid</td><td>ate user email and a</td><td>allow account acce</td><td>ss/login></td><td></td><td></td></submit:>	er to valid	ate user email and a	allow account acce	ss/login>		



DRAFT

Safety Reporting F	Portal							
Welcome Gues	t	HOME	FAQS	RELATED LINKS	CONTACT US	FEEDBACK	HELP	LOGOUT
New Guest Re	eport						RAF	:T
You have chos	en to use this portal as a Guest reporter.							
	tted as a Guest cannot be saved. Therefore, panother time, please return to the home and c			ete your repoort in full	during this session.	If you prefer to a	save your	report and
* Select the opt	ion that best describes what you want to do:							
•	Start a new report							
0	Follow-up on a report previously submitted a	s guest						
0	Follow-up on a report previously submitted as	s a logged	l in user.					
0	None of the above							
* Which of the	following best describes you?							
0	A food Facility or responsible party that man	ufactures,	processes	, packs, or holds food	who is submitting a	reportable food	l report	
0	A federal, state, or local public health official	who is sub	mitting a re	eportable food report	involving human and	d/or animal food		
0	A veterinarian or veterinary staff member v	vho is subn	nitting a pro	oduct problem and/or	adverse event rep	ort involving pet	food	
0	A consumer or concerned citizen who is subr	mitting a p	roduct prob	olem and/or adverse e	event report involvi	ng pet food		
0	A marketing authorization holder (manufactur	rer) for an	animal dru	g who is submitting a p	roduct problem and	d/or an adverse	event rep	oort
0	A Clinical trial primary investigator or resear	cher who	needs to re	eport an adverse ever	nt involving a gene	research study		
0	A healthcare professional submitting a produ	ct problen	n and/or he	alth-related problem i	nvolving a tobacco	product		
0	A consumer or concerned citizen who is sub-	mitting a p	roduct prob	olem and/or health-rel	ated problem invol	ving a tobacco p	roduct	
0	None of the above describes me							
_								
	Begin Exit							

My Report History

My Account

My Reports

Draft Reports Click column header to sort the column

Date Saved (EST)		Report ID	Title	Туре
• 01/17/2012 05:39:4	41 PM	FPSR137 (I)	Test CTP Initial	Voluntary Tobacco Product Report
O 12/19/2011 08:45:33 AM		FPSR100 (F)	Cigar Leaves	Voluntary Tobacco Product Report
Start New Report	Edit De	elet		l< < Page 1 of 1 > >l

- <Start New Report: Go to the CTP Report Introduction Page>
- <Edit: Load the selected Draft report and allow user to Edit the Draft report>
- <Delete: Allow user to Delete selected Draft report>

Submitted Reports Available for Follow-Up Click column header to sort the column

Da	te Submitted (EST)	Report ID	ICSR#	Title	Туре
⊚	01/17/2012 05:39:41 PM	FPSR111 (I)	FPSR111 (I)	Test CTP Initial	Voluntary Tobacco Product
0	12/25/2011 09:45:33 AM	FPSR118 (F)	FPSR118 (F)	Snuff Product Package	Voluntary Tobacco Product
			_		

Start Follow-Up Report

View PDF

l< < Page 1 of 1 > >l

- <Start Follow-Up Report: Load the selected report and start follow-up from the CTP Report
- <View: Load the selected report and in View mode starting from the CTP Report
- <View PDF: Load the selected report's PDF and display the submitted PDF>



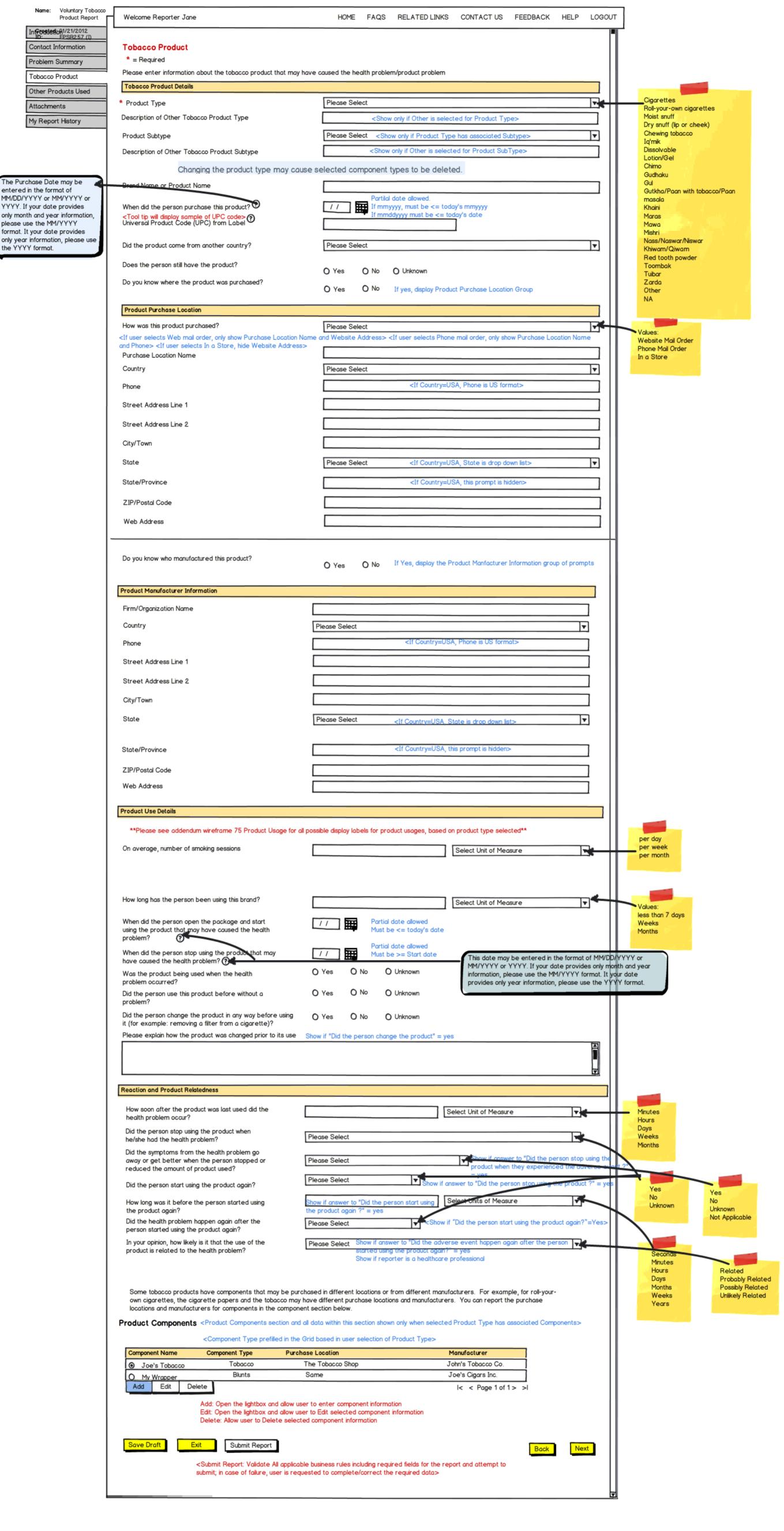
Exit

Name: Voluntary Tobacco Product Report FPSR257 (I)	Welcome Reporter Jane HOME FAQS RELATED LINKS CONTACT US FEEDBACK	(HELP	LOGOUT
Created: 01/21/2012	Introduction		
Contact Information	*=Required	RAF	
Problem Summary Tobacco Product Other Products Used Attachments My Report History	Tobacco Product Reports are for healthcare professionals and consumers to report on FDA-regulated and non-regulated tobacco products for co U.S. Please be advised that under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement or representation to the U.S subject to criminal penalties. This report has up to six sections. After you answer the questions on this page, you may complete the other pages in any order. The amount of ti complete this report will vary depending upon the information you have to provide. As you complete each field, your responses are automatically statis report, you must complete all required fields that are marked with a red asterisk. Please note: This report is not considered an admission that a product caused or contributed to serious injury, illness or death. This report shall be section 756 of the Food, Drug, and Cosmetic Act 21 U.S.C. 379v and may be accompanied by a statement, which shall be part of any report reled disclosure, that denies that the report constitutes an admission that the product involved caused or contributed to a death, serious injury, or seriou upload such a statement as an attachment to this report, if desired. *Create a name to help you find this report in the future (max length 50 characters)	. Governme me required aved. To sul considered a ased for pub	nt is to bmit under
	What type of report are you submitting? If a person experienced a health problem from use of a tobacco product, select Adverse Event (health problem). If the product had a bad smell, bad taste, foreign material in it, or some other problem, select Product Problem. If there was a health problem and a product problem, select Both. Original Source Individual Case Safety Report Number Original Submission Date Responding to a FDA request? Follow-up Reason O Adverse Event (health problem) O Product Problem O Both System generated, read only; show only if report = follow-up> O Yes O No System Generated; if report = follow-up> O Yes O No Show only if the Report is a Follow-up> O Yes O No Submit Report: Validate All applicable business rules including required fields for the report and attempt to submit; in case of failure, user is requested to complete/correct the required data>	Read Only; s	

Name: Voluntary Tobacco Product Report ID: FPSR257 (I)	Welcome Reporter Jane	HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT
Introduction Contact Information	Contact Information *=Required	
Problem Summary Tobacco Product	·	reference to this report, and in accordance with the Department of Health and Human Services of for your reference.
Other Products Used	Your Contact Information	
Attachments	Check here if you wish to remain anonymous	<if all="" asked="" checked,="" code;="" guest="" hide="" if="" only="" postal="" prompts="" reporter="" through="" zip=""></if>
My Report History	First Name If registered user, First Name, Last Name, Email, Confirm email, Country, Phone. Street Address 1, Street Address 2, City/Town, State, Zip are prefilled from the registration information.>	
	May the FDA contact you to follow-up if necessary?	Yes O No <if is="" next="" prompt="" shown="" yes,=""></if>
	Preferred method of contact	O Email <if email="" information="" is="" required="" selected,=""> O Phone <if information="" is="" phone="" required="" selected,=""> O Address <if address="" information="" is="" required="" selected,=""></if></if></if>
	Email	
	Confirm Email	
	Country	Please Select <if and="" down="" drop="" format="" is="" list="" phone="" state="" us="" usa,="" uses=""> ▼</if>
	Phone	<if country="USA," format="" is="" phone="" us=""></if>
	Street Address Line 1	
	Street Address Line 2	
	City/Town	
	State	Please Select <if country="USA," down="" drop="" is="" list="" state=""></if>
	State/Province	<if country="USA," hidden="" is="" prompt="" this=""></if>
	ZIP/Postal Code	
	Sender Category	<read "which="" based="" best="" consumer="" describes="" field.="" following="" healthcare="" of="" on="" only="" or="" prefill="" professional="" selection="" the="" user="" with="" you?"="" ▼=""></read>
	Organization	<shown a="" healthcare="" if="" is="" only="" prefilled="" professional,="" registered="" user=""></shown>
	Title	<shown a="" healthcare="" if="" is="" only="" prefilled="" professional,="" registered="" user=""></shown>
	Are you the person who experienced health problems associated with a tobacco product?	O Yes O No <hidden if="" problem="" product=""></hidden>
	Please describe your relationship to the person who experienced the health problem	<hidden for="" healthcare="" professionals=""> <hidden "are="" adverse="" event?"="Yes" experienced="" from="" if="" person="" symptoms="" the="" who="" you=""></hidden></hidden>
	Healthcare professional type	Please Select <shown a="" healthcare="" if="" is="" only="" prefilled="" professional,="" registered="" user=""> ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■</shown>
	Describe other	Show if healthcare professional type = other, Shown only if user is a Healthcare Professional, prefilled if registered user>
	Save Draft Submit	Back Next

DRAFT

Name: Voluntary Tobacco Product Report ID: FPSR257 (I)	Welcome Reporter Jane	HOME FAQS RELATED LINKS	CONTACT US FEEDBACK HELP	LOGOUT	
Created: 01/21/2012 Introduction	Problem Summary			DRAFT	
Contact Information Problem Summary	*=Required Affected Person				
Tobacco Product					
Other Products Used Attachments	Gender	O Male O Female			
My Report History	Pregnant	O Yes O No O Unknown	<show female="" gender="" if="" is="" only=""></show>		
	Race (select one or more)	☐ American Indian or Alaska Native☐ Asian			
		 □ Black or African American □ Native Hawaiian or Other Pacific Islande 	er		
		☐ White			
	Ethnicity	O Hispanic or Latino			
		O Not Hispanic or Latino	The Birth Date may be entered in the form	prmat of MM/DD/YYYY or	
	Birth date of the person who experienced the health problem 💇	<partial allowed="" date=""></partial>	MM/YYYY or YYYY. If your date provides please use the MM/YYYY format. It your or information, please use the YYYY format.	ır date provi des only year	
	Age of the person when the health problem occurred		Select Unit of Measure		
	Please list any known pre-existing health problems for the affected	d person			
	✓ ABC				
	Problem Description				
		pearance, look, smell, or taste is wrong or not ild safety issue	as expected		
	<shown both="" if="" only="" or="" problem="" report="" type="Product"></shown>	maged, broken or defective product, accesory reign material (something is present that does			
	☐ Inc	correct use - accidental (prodcut was used inco	rrectly by accident)	This date may be entered in the format of MM/DD/YYYY or	
		beling or instructions for th euse are incorrect, mber of items in package is wrong	misleading or difficult to understand	MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. It your date provides only year information, please use the YYYY format.	
	□ Pro	her product problem not listed oduct functions in a way that is unexpected or in			
		oduct mixup (product was mistaken for another rong product in package	product or accidentally substitute for another	er product)	
	Please provide the health problem/product problem s	start and end dates, or how long the health p	problem lasted		
		*Partial dutes will be accep	nted Minyyyyy and YYYY; Start Date cannot	This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and year	
	Health Problem/Product Problem Start Date ① Health Problem/Product Problem End Date ②	/ / be after today's date>	eted MM/YYYY and YYYY; End date cannot b	information, please use the MM/YYYY format. It your date provides only year information, please use the YYYY format.	
	How long did the health problem event last?	before the start dates	<make for<br="" if="" measure="" of="" required="" unit="" value="">long did the adverse event last?" = not blank Select Unit of Measure</make>		
	* What are the main symptoms or health problems (select up to 5)		_		
	Abnormal heart rhythm	☐ Achy joints			
	☐ Additction to nicotine/toabbco product☐ Anxiety☐ <insert as="" data="" full="" in="" list="" of="" provided="" requirements="" the="" values=""></insert>	Allergic reaction Aortic aneurysm	es as provided in the data requirements>		
	Upper respiratory infection/cold Use with another product led to a problem	Urinary tract infecti	on		
	□ Vomiting	Wheezing	,		
	*Please Describe the Health Problem or Product Problem:				
	ABC				
	Do any of these apply to the health problem? (Select one or more)	Death Disability			
		☐ Life Threatening ☐ Birth Defect			
		Hospitalization			
	If none of the above is selected along with another checkbox, give user	☐ Treatment Received ☐ Multiple Deaths and Serious Injuries			
	e message: Please check your answer. If "None of the above" is elected, all other boxes must be blank>	☐ Pediatric Death☐ None of the Above			
	Outcome to date	Please Select		Hidden if outcome = death>	
	Was the person taken to an emergency facility?	O Yes O No O Unknown			
	Was the person evaluated by a healthcare	O Yes O No O Unknown			
	professional? Date the person was first seen by a healthcare professional for this health problem	/ / <partial allowed="" date=""></partial>	•	This date may be entered in the format of MM/DD/YYYY or MM/YYYY or YYYY. If your date provides only month and ye information, please use the MM/YYYY format. It your date	
	Has this person ever had a similar health problem or product problem			provides only year information, please use the YYYY format	
	Please describe the similar health problem or product problem	J 160 J 100			
	ABC				
	Please describe any treatment the person received including result	ts of any tests (such as x-rays, lab results, or t	olood work)		
				<u>=</u>	
	ABC		This date may be entered in the format		
	Date of Death 🕜	/ / Partial date allowed>	MM/YYYY or YYYY. If your date provide information, please use the MM/YYYY for provides only year information, please use the matter of the provides only year information, please use the matter of the provides only year information.	vides only month and year Y format. It your date	
	Reported Cause of Death				
	Traported dauge of Deutil				
	Own Date			No.	
	Save Draft Exit Submit Report		Back	Next	
		usiness rules including required fields for the re ed to complete/correct the required data>	eport and attempt to		
	1	•		11	





Name:

the YYYY format.

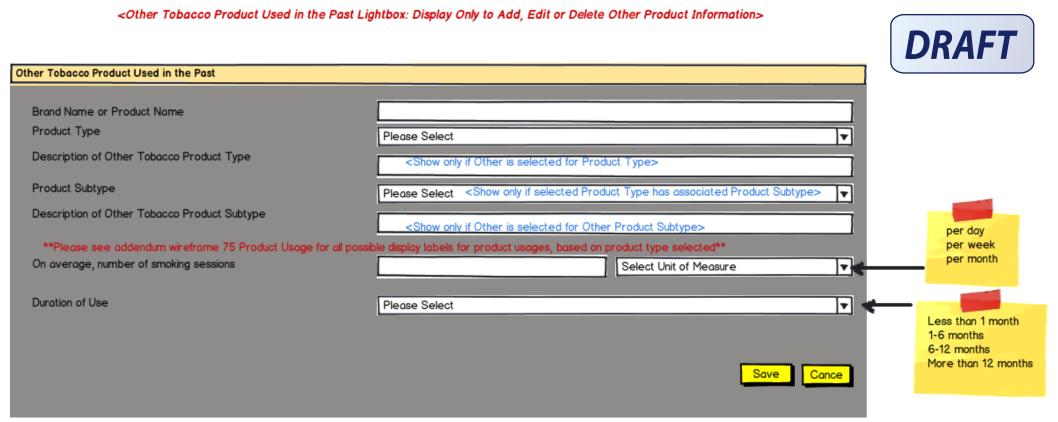
O Unknown

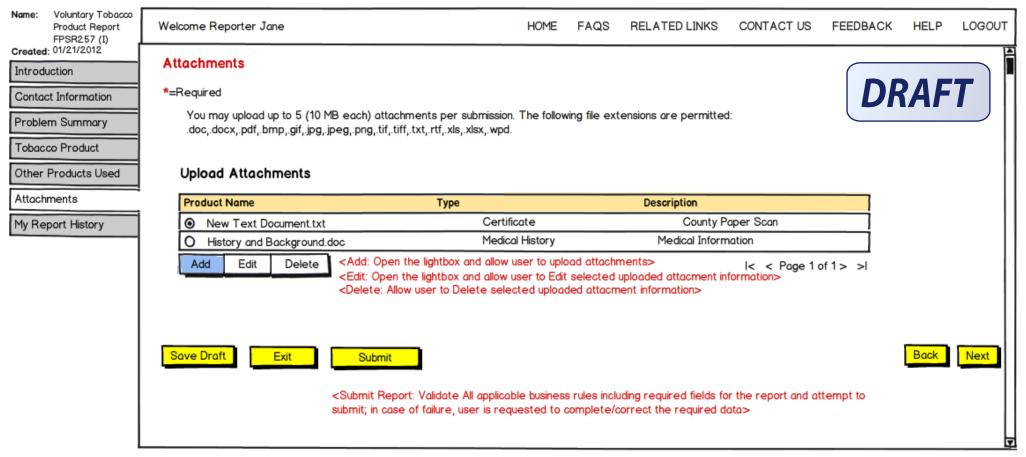
<product all="" and="" components="" data="" section="" th="" with<=""><th>in this section shown only when selected Product Type has associated Components></th><th></th><th></th></product>	in this section shown only when selected Product Type has associated Components>		
Component Detail			
Brand Name or Component Name		\neg	
Component Type	Please Select <filtered based="" on="" product="" selection="" set="" type="" user="" value=""></filtered>	┰	
Description of Other Tobacco Component	<shown component="" if="" in="" is="" only="" other="" selected="" type=""></shown>		This date may be entered in the format of MM/DD/YYYY or
When did the person purchase this component?	/ / Partilal date allowed>		MM/YYYY or YYYY. If your date provides only month and year information, please use the MM/YYYY format. It your date
<tool code="" display="" of="" sample="" tip="" upc="" will=""> Universal Product Code (UPC) from Label</tool>		\Box (provides only year information, please use the YYYY format.
Did the component come from another country?	Please Select		Yes
Does this person still have the component?	O Yes O No O Unknown		No Unknown
Do you know where the component was purchased?	O Yes O No <if component="" group="" location="" purchase="" show="" yes,=""></if>		and the second second
Component Purchase Location			
How was this component purchased? <if <if="" a="" address="" hide="" in="" location="" mail="" name="" only="" order,="" phone="" purchase="" selects="" show="" store,="" user="" web="" website=""> Purchase Location Name</if>		□ *	Values: Website Mail Order Phone Mail Order In a Store
Country	Please Select	₩	
Phone			
Street Address Line 1			
Street Address Line 2			
City/Town			
State	Please Select <if country="USA," down="" drop="" is="" list="" state=""></if>	₩	
State/Province	<if country="USA," hidden="" is="" prompt="" this=""></if>		
ZIP/Postal Code			
Web Address			
Do you know who manufactured this component?	O Yes O No <if component="" group="" information="" manufacturer="" show="" yes,=""></if>		
Component Manufacturer Information			
Firm/Organization Name			
Country	Please Select	▼	
Phone			
Street Address Line 1			
Street Address Line 2			
City/Town			
State	Please Select <if country="USA," down="" drop="" is="" list="" state=""></if>	₩	
State/Province	<if country="USA," hidden="" is="" prompt="" this=""></if>		
ZIP/Postal Code			
Web Address			DRAFT
	Save	•	

	tary Tobacco		
FPSR:	uct Report 257 (I)	Welcome Reporter Jane HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT	
Created: 01/21/ Introduction	72012	Other Products Used	
Contact Infor	rmation	*=Required	
Problem Sum	nmary	Is the affected person currently using other tobacco products (within past month)? • Yes O No O Unknown < If yes. show Other Tobacco Products Currently Used group>	
Tobacco Pro	oduct	tobacco products (within past month)? Yes O No O Unknown If yes, show other robacco reducts out entry used group Select Add button below if the person uses other tobacco products	
Other Produc	cts Used	Other Tobacco Products Currently Used	
Attachments	;	Brand Name/Product Name	
My Report Hi	listory	⑥ Cigarettes	
		O Cigars	
		Add: Open the lightbox and allow user to enter Other Product Used information> < Page 1 of 1 > > < Edit: Open the lightbox and allow user to Edit selected Product information> < Delete: Allow user to Delete selected Product information>	
		Has the affected person used other tobacco products on a regular basis in the past? O No O Unknown < If yes, show Other Tobacco Products Used in the Past group.	
		Other Tobacco Products Used in the Past	
		Select Add button below if the person used other tobacco products in the past Brand Name/Product Name	
		Chewing Tobacco	
		O Snus	
		Add Edit Dele <add: allow="" and="" enter="" information="" lightbox="" open="" other="" product="" the="" to="" used="" user=""> I< < Page 1 of 1> >I < Page 2 of 1> >I < Page 3 of 1> >I < Pag</add:>	
		Does the person who had the adverse event also drink alcohol?	<5 drinks/week
		How many drinks per week? Triedse Select Collow only it boes the person who had the daverse event also drink disorior: — resz	5-6 drinks/week 7+ drinks/week
		Please describe anything else you think the FDA should know about this health problem	
		ABO Medications, Vitamins and Supplements Please give us information about prescription medications, OTC medications, vitamins and/or supplements taken around the time of the	
		health problem	
		Save Draft Exit Submit	
		<submit all="" and="" applicable="" attempt="" business="" case="" complete="" correct="" data="" failure,="" fields="" for="" in="" including="" is="" of="" report="" report:="" requested="" required="" rules="" submit;="" the="" to="" user="" validate=""></submit>	

<Other Tobacco Product Currently Used Details Lightbox: Display Only to Add, Edit or Delete Other Product Information>

Other Tobacco Products Currently Used Details		DRAFT
Other Tobacco Products Currently Osea Decais		
Brand Name or Product Name		
Product Type	Please Select	
Description of Other Tobacco Product Type	<show for="" if="" is="" only="" other="" product="" selected="" type=""></show>	
Product Subtype	Please Select Show only if selected Product Type has associated Product Subtype>	
Description of Other Tobacco Product Subtype	<show for="" if="" is="" only="" other="" product="" selected="" subtype=""></show>	
Please see addendum wireframe 75 Product Usage for all post On average, number of smoking sessions	sible display labels for product usages, based on product type selected Select Unit of Measure	per day per week per month
Duration of Use	Please Select ▼	Less than 1 month 1-6 months 6-12 months More than 12 months
	Save	





<File Attachment Lightbox: Display Only to Add, Edit or Delete Attachment Information>

