

Tobacco Product Investigator's Report wireframes  
December 2015

# 1 My Reports - TIR

**Safety Reporting Portal**

HOME | FAQs | RELATED LINKS | CONTACT US | FEEDBACK | HELP | LOGOUT

**My Reports**

Group ID: <Group ID>  
<Reporter Role>

Member: Self

**Draft Reports**

Click column header to sort the column

Date Saved (EST)	Report ID	Title	Report Type Description
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (I)	<Title provided by user>	<Defined report name> Created By:<Reporter name>

Start New Report | Edit | Delete | View | Refresh List | < <Page 1 of 1 > |

Please make sure an appropriate group is selected from the left navigation menu before creating a report

**Submitted Reports Available for Follow-Up**

Submitted as of (mm/dd/yyyy or mm/yyyy): ICSR Number (please enter the number only): Title

Search | Reset

Member: Self

Click column header to sort the column

Date Submitted (EST)	Report ID	ICSR#	Title	Report Type Description
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (I)	<ICSR number> (I)	<Title provided by user>	<Defined report name> -<Protocol Number> Submitted By:<Reporter name>
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (F)	<ICSR number> (F)	<Title provided by user>	<Defined report name> -<Protocol Number> Canceled By:<Reporter name>

Start Follow-up Report | Clone Report | View | View PDF | Refresh List | < <Page 1 of 1 > |

Cloning is a convenience feature which creates a new draft report using the responses from a previously submitted report.

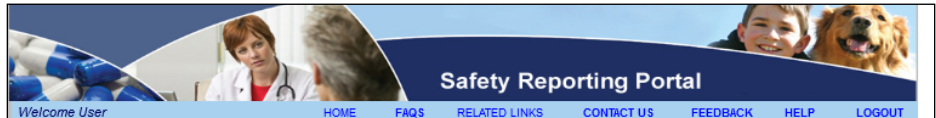
The prepopulated fields should be closely examined for their accuracy and relevance with respect to the new report to be submitted; they can be edited as needed.

Note that cloning is not the same as creating a follow-up report.

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

### 3 My Account -TIR



## My Account

\* = Required Field

### Reporter Information

[Change Password and Security Question](#)

\* Reporter Role: <pre-selected>

\* First Name: <First Name>

\* Last Name: <Last Name>

Job Title: <Job Title>

\* Research Reporter Type (select all that apply)

- Investigator
- Clinical Study Sponsor
- Study Monitor
- Other

Describe other Research Reporter Type: \_\_\_\_\_

\* Email Address (this will be your Login ID): <email address>

\* Primary Phone: <primary phone number>

Other Phone: <other phone number>

Fax: <fax number>

Primary Phone - country code: \_\_\_\_\_

Primary Phone - number/extension: \_\_\_\_\_

### Reporter Address

\* Organization Name: <Organization Name>

\* Country: Please select

\* Street Address Line 1: <Street Address Line 1>

Street Address Line 2: <Street Address Line 2>

\* City/Town: <City/Town>

\* State: Please select

State/Province: \_\_\_\_\_

\* ZIP/Postal Code: <ZIP Code>

### Study Information

\* Study Name and/or Identifier: \_\_\_\_\_

A  
 B  
 C

\* Study Sponsor Name: \_\_\_\_\_

Sponsor Organization Name: \_\_\_\_\_


Name of Principal Investigator: \_\_\_\_\_

If applicable, click the "My Groups" link to view all groups you belong to.

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

# 4 Introduction - TIR



Name: Tobacco Product Report (Research Study)  
ID: <ID>  
Created: <date>

- Introduction 23
- Contact Information 24
- Problem Summary 25
- Research Summary 26
- Study Tobacco Products 27
- Other Tobacco Products Used 28
- Additional Information 29
- Attachments 30
- My Report History 31

OMB Approval Number:  
<OMB Approval #>  
OMB Expiration Date:  
<date>  
OMB Burden Statement

## Introduction

**\*Required Field**

**"How do I use this SRP path to submit a report?"**  
When possible, please submit a separate report for each affected person. After this page, you can fill in the rest of the pages of the report in any order. The system will only accept a report if you fill in all fields marked \*. The system will save your entries when you click the "Next" button on each page. If you cannot finish the report in one sitting, you can save it and finish it later if you set up an account.

**"What happens when I submit a report?"**  
FDA staff will review your report. FDA may contact you if we need more information and if you give us a way to reach you, but most reporters will not hear back from FDA. **You will not get health advice or health care from FDA** – please call or see your local doctor or clinic if needed.

Account holders can log into their account to change or cancel a report. See the [HHS Privacy Policy Notice](#) to learn more about how we guard your privacy and when we share reports.

Some reports are posted for public viewing after removing personal and confidential information ( See [FOIA reading room](#)).

Please note: This report is not considered an admission that a product caused or contributed to the event. This report shall be considered to be a report under section 756 of the Food, Drug, and Cosmetic Act (21 U.S.C. 379v).

**What Not to Report using this Safety Reporting Portal (SRP) pathway:**

- Comments, concerns, advice, or questions to FDA - see the [FDA](#) or [CTP](#) home pages for contacts. Contact CTP by email at [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov) or phone at 301-796-9200 or toll-free phone at 1-877-287-1373.
- Potential tobacco-related violations of the Food, Drug, and Cosmetic Act and associated regulations, including but not limited to unlawful sales of tobacco products, counterfeit tobacco products, product tampering, or false ads - Report these to CTP's Potential Tobacco Product Violations Reporting (PTVR) website at: <https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>

---

**Report Information**

Report Source

Describe other report source

Report ID

Regulatory Application Identifier

Master List Number

\*Date of Original Receipt to CTP

\*Create a name to help you find this report in the future (max length: 50 characters)

\*What type of report are you submitting?

Original Source Individual Case Safety Report Number

Original Submission Date

Follow-Up Reason(s) (select all that apply)

Are you sure you want to cancel the previous report?

Describe the reason for cancelling the report

Please Select

Health-Related Problem associated with a tobacco product (not associated with a product problem or defect)  
 Product Problem or Defect (not associated with a health-related problem)  
 Both (health-related problem that is also associated with a product problem or defect)









<pre-filled>

<pre-filled>


Additional Information  
 Correction  
 Response to FDA Request  
 Cancel Submitted Report (the system has compiled the original report and its follow-up reports (if any) into a single report)  
 Reactivate Canceled Report  
 Other

Yes    No

**Tobacco Product Investigator's Report wireframes  
December 2015**

	 	
	 	
	 	
	 	
	<p>Describe the other reason for submitting this follow-up report</p>	20
	<p>Summarize reason for reactivating the canceled report</p>	24
	<p>Additional notes about this report:</p>	22
	<p>Save Draft    Exit    Submit Report</p>	33
		Next

# 5 Contact Information - TIR



Welcome User    HOME    FAQs    RELATED LINKS    CONTACT US    FEEDBACK    HELP    LOGOUT

Name: Tobacco Product Report (Research Study)  
ID: <ID>  
Created: <date>

**Introduction**

**Contact Information**

**Problem Summary**

**Research Summary**

**Study Tobacco Products**

**Other Tobacco Products Used**

**Additional Information**

**Attachments**

**My Report History**

OMB Approval Number:  
<OMB Approval #>

OMB Expiration Date:  
<date>

OMB Burden Statement

## Contact Information

\* = Required Field

**Please note:** Your contact information will be used by the FDA only in reference to this report, and in accordance with the Department of Health and Human Services privacy policy. There is a link to this policy on the bottom of this page for your reference.

This section is pre-filled from your registered account. Changes made in this section are for this report only, and will not change the information on the My Account page.


Your Contact Information

First Name	<input type="text" value="&lt;First Name&gt;"/>	1
Last Name	<input type="text" value="&lt;Last Name&gt;"/>	2
Email (If pre-filled, changing this email address will not change your Login email ID)	<input type="text" value="&lt;email address&gt;"/>	3
Confirm Email	<input type="text" value="&lt;email address&gt;"/>	4
Country	<input type="text" value="Please select"/>	5
Phone	<input type="text" value="&lt;Phone Number&gt;"/>	6
Street Address Line 1	<input type="text" value="&lt;Address Line 1&gt;"/>	7
Street Address Line 2	<input type="text" value="&lt;Address Line 2&gt;"/>	8
City/Town	<input type="text" value="&lt;City/Town&gt;"/>	9
State	<input type="text" value="Please select"/>	10
State/Province	<input type="text" value="&lt;State/Province&gt;"/>	11
Zip/Postal Code	<input type="text" value="&lt;ZIP/Postal Code&gt;"/>	12
* Sender Category	<input type="text" value="Research (FdaTIR)"/>	13
* Organization Name	<input type="text" value="&lt;Organization Name&gt;"/>	14
Job Title	<input type="text" value="&lt;Job Title&gt;"/>	15
* Research Reporter Type (select all that apply)	<input type="checkbox"/> Investigator 16 <input type="checkbox"/> Clinical Study Sponsor <input type="checkbox"/> Study Monitor <input type="checkbox"/> Other	
Describe other Research Reporter Type	<input type="text"/>	17

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

# 6 Problem Summary


Safety Reporting Portal

Welcome User
HOME
FAQS
RELATED LINKS
CONTACT US
FEEDBACK
HELP
LOGOUT

**Name:** Tobacco Product Report (Research Study)  
**ID:** <ID>  
**Created:** <date>

**Problem Summary**

**Research Summary**

**Study Tobacco Products Used**

**Other Tobacco Products Used**

**Additional Information**

**Attachments**

**My Report History**

OMB Approval Number:  
<OMB Approval #>  
OMB Expiration Date:  
<date>  
OMB Burden Statement

### Problem Summary

\* = Required Field

**Affected Person**

**Participant Identifier Code**

**Gender**  
 Male  Female

**Pregnant**  
 Yes  No  Unknown

**Ethnicity**  
 Hispanic or Latino  
 Not Hispanic or Latino  
 Unknown

**Race (select all that apply)**  
 American Indian or Alaskan Native  
 Asian  
 Black or African American  
 Native Hawaiian or Other Pacific Islander  
 White  
 Unknown

**Birth date of the person who experienced the health problem**

For the following field, enter a number in the first field, followed by a Unit of Age from the dropdown field. If the affected person was an unborn child, select "unborn child" from the Unit of Age field, and leave the number field blank.  
When a Unit of Age other than "unborn child" is selected, a number must be entered in the number field. If no number is entered for age, then the Unit of Age field must also be empty or "unborn child" should be selected.

**Age of the person when the problem occurred**

**Please list any known pre-existing health problems for the affected person.**

**Medications and Supplements**

**Please list the prescription medications, over-the-counter medications, vitamins, and/or supplements taken around the time of the health problem.**

**Problem Description**

**Problem Start Date**

**Problem End Date**

\* Please describe the health problem or product problem. The Attachments page will accept uploads of any records, pictures, or other information.

**Product Problem Type (select all that apply)**

<input type="checkbox"/> Appearance, look, smell or taste issue	<input type="checkbox"/> Label or instruction issue
<input type="checkbox"/> Child safety hazard	<input type="checkbox"/> Leaked or spilled
<input type="checkbox"/> Damaged, broken or defective product, part, accessory, or package	<input type="checkbox"/> Overheated
<input type="checkbox"/> Exploded, caught on fire, or burned abnormally	<input type="checkbox"/> Product failed or did not work correctly
<input type="checkbox"/> Foreign material (something is present that does not belong)	<input type="checkbox"/> Wrong number of items in package
	<input type="checkbox"/> Wrong product in package
	<input type="checkbox"/> Other

# Tobacco Product Investigator's Report wireframes

## December 2015

Hard to open or use

Please describe the other product problem 14

What are the main symptoms or health problems? 15

MedDRA Term

Click on the Add button to add an item

< <Page 1 of 1 >

Do any of these apply to the health problem? (Select one or more) 16

Death

Lasting disability or other permanent health problem

Life Threatening

Birth Defect

Hospitalization (Overnight or Longer)

Needed Treatment to Prevent Permanent Harm

Other serious medical event

Emergency Room Visit without Hospital Admission

None of the Above

Reported Cause of Death 17

Treatment Received (select all that apply): 18

None

Healthcare Professional Visit

Self-Treated

Other

Please describe treatment the person received, including results of any tests (such as x-rays, lab results, or blood work). The Attachments page will accept uploads of any records, pictures, or other information. 19

How long did the health problem last (if resolved), or (if ongoing) how long has it lasted so far? 20

Select Unit of Time

What is the current status of the health problem? 21

Please Select

Describe other current status of health problem 22

Does the health problem include a secondhand or thirdhand effect (i.e. a health problem affecting someone other than the person using the study tobacco product)? 23

Yes  No

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

## 7 What are the main symptoms or health problems?

**What are the main symptoms or health problems?**

Type all or part of the word(s) that describe your health problem to see a list of possible terms (limited to 100 terms). If you cannot find a good match, use a different search word or select "Other."


MedDRA Term

Save Cancel

The image shows a wireframe of a web form. At the top, there is a title bar with the text 'What are the main symptoms or health problems?'. Below this is a paragraph of instructions: 'Type all or part of the word(s) that describe your health problem to see a list of possible terms (limited to 100 terms). If you cannot find a good match, use a different search word or select "Other."' Below the instructions is a search input field with the placeholder text 'Type to search and select'. To the left of the input field is the label 'MedDRA Term'. At the bottom right of the form are two buttons: 'Save' and 'Cancel'. Red callout boxes with numbers 1, 2, and 3 are placed over the search input field, the 'Save' button, and the 'Cancel' button respectively.



# 8 Research Summary



## Safety Reporting Portal

Welcome User   [HOME](#)   [FAQS](#)   [RELATED LINKS](#)   [CONTACT US](#)   [FEEDBACK](#)   [HELP](#)   [LOGOUT](#)

Name: Tobacco Product Report (Research Study)

ID: <ID>

Created: <date>

- Introduction
- Contact Information
- Problem Summary
- Research Summary
- Study Tobacco Products
- Other Tobacco Products Used
- Additional Information
- Attachments

**My Report History**

OMB Approval Number: <OMB Approval #>

OMB Expiration Date: <date>

OMB Burden Statement

### Research Summary

**\* = Required Field**

Add relevant FDA-assigned submission tracking number(s) (STN) for each study tobacco product.

**Submission Tracking Number(s)** 1

Tracking Number Type	Tracking Number	STN
<input type="radio"/>		

Click on the Add button to add an item

Add
Edit
Delete
|< <Page 1 of 1 >

FDA-assigned Protocol Number 2

**\* Study Name and/or Identifier** 3

**\* Study Sponsor Name(s)** 4

**Name of Principal Investigator** 5

**Clinical Trial Site where problem occurred or was discovered** 6

**Institutional Review Board (IRB) Name** 7

Select the entities that have been notified of this problem (select all that apply) 8

Data Safety Monitoring Board (DSMB)

Institutional Review Board (IRB)

Product Manufacturer

Study Sponsor

Other

**Describe others notified** 9

**Brief description of study** 10

**Status of the study** 11

**What is the reason for suspension?** 12

Describe the reason for study suspension 13

# Tobacco Product Investigator's Report wireframes December 2015

13

A  
B  
C ✓

Was this event unexpected?  Yes  No 14

Serious and unexpected events only: Describe any known similar or related problems previously occurring in the course of this study or related studies.

15

A  
B  
C ✓

Status of the investigation of this problem 16

Please Select

Describe investigation or reason for no investigation

17

A  
B  
C ✓

18

Select the actions that are in process or being considered as a result of the problem(s) reported. (select all that apply)

- Informed consent modification
- Investigator's brochure modification
- IRB action to ensure the protection of human subjects
- Study protocol modification
- Suspension of the study
- Other

Describe actions that are in process or being considered as a result of the problem(s) reported.

19

A  
B  
C ✓

Save Draft   Exit   Submit Report   < Back   Next >

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

## 9 Submission Tracking Number Details

**Submission Tracking Number Details**

Tracking Number Type  1

Tracking Number  2

Other Tracking Number  3


Hit the Tab key to auto-populate the STN field. STN will not populate if Tracking Number Type is Other.

STN  4

Save 5 Cancel 6

A wireframe of a web form titled "Submission Tracking Number Details". The form contains several input fields and buttons. A vertical line of blue numbered callouts (1-6) is positioned on the right side of the form, pointing to specific elements: 1 points to the "Tracking Number Type" dropdown menu; 2 points to the "Tracking Number" text input field; 3 points to the "Other Tracking Number" text input field; 4 points to the "STN" text input field; 5 points to the "Save" button; and 6 points to the "Cancel" button. A text box with a light gray background contains the instruction: "Hit the Tab key to auto-populate the STN field. STN will not populate if Tracking Number Type is Other."

# 10 Study Tobacco Products



## Safety Reporting Portal

Welcome User   [HOME](#)   [FAQS](#)   [RELATED LINKS](#)   [CONTACT US](#)   [FEEDBACK](#)   [HELP](#)   [LOGOUT](#)

**Name:** Tobacco Product Report (Research Study)  
**ID:** <ID>  
**Created:** <date>

**Introduction**

**Contact Information**

**Problem Summary**

**Research Summary**

**Study Tobacco Products**

**Other Tobacco Products Used**

**Additional Information**

**Attachments**

### Study Tobacco Products

**\* = Required Field**

**\* Do you know which study tobacco product was associated with the problem?**

Yes 1

No, the subject was exposed to more than one study tobacco product that may have been associated with the problem

No, identity of the study tobacco product(s) to which the subject was exposed is unknown

No, subject was not exposed to any study tobacco product

No, other

**Note: If the subject is/was concurrently using nonstudy tobacco product(s), provide this information on the Other Tobacco Products Used page.**

**Describe other reason you do not know which study tobacco product was associated with the problem**

A B C

**What is the marketing status of the study tobacco product(s) in the United States? (select all that apply)**

Legally Marketed Tobacco Product 3

Investigational Tobacco Product

Other

**Describe other study tobacco product marketing status**

A B C

**Who is experiencing this problem?**

Subject    Other 5

**Please describe the person experiencing the problem**

A B C

Use the "Add" button in the table below to individually enter information for each study tobacco product that the subject received during the course of the study. If you are uncertain which product(s) a subject has received, enter information for all of the study tobacco products that the subject may have received.

Review all product and related product part information carefully before submitting this report, to ensure accurate reporting. Clicking on a radio button and selecting the Edit button will allow you to change any answers for the selected Product Type in this section.

This section is required unless you indicated above that the subject was not exposed to any study tobacco product AND you are not reporting a product problem.

**Study Tobacco Product(s)** 7

Product Type	Product Subtype	Brand Name/Product Name
<input type="radio"/>	<input type="text"/>	<input type="text"/>
Click on the Add button to add an item		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

|< <Page 1 of 1 >|

# Tobacco Product Investigator's Report wireframes

## December 2015

Some tobacco products have parts that may have been purchased in different locations or from different manufacturers. You can report the purchase locations and manufacturers for product part(s) in the section below. 10

**Study Tobacco Product Part(s) for <Product Type>** 8

Product Part Type	Product Part Name	Purchase Location	Manufacturer
<input type="radio"/>			

Click on the Add button to add an item

[< Page 1 of 1 >]

I have reviewed the details and product parts listed for each study tobacco product, if available, and made any necessary corrections. 9

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

# Tobacco Product Investigator's Report wireframes December 2015

## Study Tobacco Product Details

Enter information about a single study tobacco product that may have caused the problem. When you have completed and saved this section, you can click the "Add" button in the Tobacco Product(s) table to add information about any additional study products.

Information and pictures to assist in identifying tobacco products can be found [here](#) 38

### \* Study Tobacco Product Type

- Cigarette 1
- Roll-your-own cigarette
- Bidis, Cloves, Herbal Cigarettes with tobacco
- Electronic cigarette, electronic nicotine or vaping product (E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
- Tobacco Heating System (heats tobacco leaf not liquid)
- Waterpipe (also known as hookah, narghile, shisha, or goza)
- Cigar (premium or large)
- Small Cigar, Little Cigar or Cigarillo
- Pipe or pipe tobacco
- Snuff (dry or moist for use in nose or mouth)
- Snus (pouches or loose)
- Chewing tobacco (loose leaf chew, plug, twist/roll)
- Gutka (or Gutkha), Betel Quid with Tobacco
- Mixture of tobacco with spices, herbs, nuts, fruit, plant leaves, etc. (used for chewing)
- Dissolvable (for example, strips, sticks, orbs)
- Nicotine Lotions or Gels (applied to the skin)
- Tobacco Powder, gel or paste applied to the teeth, gums, or mouth
- Other

Changing the product type may cause selected product part types to be deleted.

Description of other study tobacco product type 2

Study Tobacco Product Subtype 3

Please Select 3

Describe other electronic cigarette, electronic nicotine or vaping product subtype 4

A  
B  
C

Describe other cigar type 5

Describe homemade electronic vaporizer device 6

A  
B  
C

# Tobacco Product Investigator's Report wireframes

## December 2015

**Describe other snuff type** 7

**Describe other snus type** 8

**Describe other dissolvable product subtype** 9

**Describe other chewing tobacco subtype** 10

**What was the heating source for the waterpipe (also known as hookah, narghile, shisha, or goza)?** 11

Please Select

**Describe the other heating source for the hookah/shisha/waterpipe**

**What does the electronic or battery powered hookah/shisha/waterpipe look like?** 12

Please Select

**Describe what the electronic or battery powered hookah/shisha/waterpipe product looks like**

**The tobacco or shisha product used was**

A Premixed Preparation

Custom Mixed or Mixed to Order

Mixed or Modified by User or Study Personnel

**Describe the tobacco or shisha mix**

**The Waterpipe (also known as hookah, narghile, shisha, or goza) was filled with (select all that apply)**

Water

Alcohol

Other

**Describe the other waterpipe liquid used** 13

**Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe)**

Disposable (non-refillable) product

Rechargeable product

Uses prefilled cartridge, cart, cartomizers or carto.

Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user)

Uses a Tank or Tank System

Modified: the original product was modified

Power (watts) can be changed or adjusted

Voltage can be changed or adjusted

Button activated

Puff/flow activated

**How has the electronic cigarette, electronic nicotine or vaping product been modified by the user or study personnel? (select all that apply)**

The battery or power source has been changed

The heating element or atomizer has been changed

The tank system has been changed

# Tobacco Product Investigator's Report wireframes December 2015

The tank system has been changed  
 Other

**Describe other electronic cigarette, electronic nicotine or vaping product modification**

A  
S  
C ✓

**Select all that apply to the e-liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product**

Purchased in a non-refillable disposable cartridge  
 Purchased for use in a capsule, tank or refillable cartridge  
 Mixed in a shop or on-line per request or "to order"  
 Mixed or modified by the user or study personnel

14

**Describe the e-liquid mix**

A  
S  
C ✓

**Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)**

Nicotine  
 Coloring Agents  
 Flavor(s)  
 Glycerin  
 Propylene Glycol  
 Water  
 Other

**Describe other e-liquid ingredients**

**What type(s) of flavor(s) does the e-liquid contain? (select all that apply)**

Tobacco  
 Menthol  
 Mint (such as wintergreen or spearmint)  
 Clove or Spice  
 Fruit  
 Candy or Chocolate  
 Alcoholic Drink  
 Combination/Mixture of Flavors  
 Other

**Describe other e-liquid flavor(s)**

**Was the e-liquid dripped on to the atomizer or heating element?**

Yes  No  Unknown

15

**\* Full Study Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")**

A  
S  
C ✓

16

**UNIVERSAL PRODUCT CODE (UPC) from Label** ⓘ


17

**Any other identifying study tobacco product codes (for example, SKU, item/catalog number, manufacturing date/ batch code)**

18



# Tobacco Product Investigator's Report wireframes December 2015

ASC 

**Study Tobacco Product Packaging and Portions** 19

This is an optional section to provide FDA more information to identify the study tobacco product.


Cigarette Length	Please Select
Describe Other Cigarette Length	
Cigarette Size/Diameter	Please Select
Describe Other Cigarette Size/Diameter	
Package Size/# of Cigarettes per Pack	Please Select
Describe Other Cigarette Package Size	
Is this a Menthol or Regular Tobacco Cigarette?	Please Select
Provide any additional descriptive terms for the cigarettes (for example, "Blue", "Smooth", "Full Flavor", "Premium")	
Smokeless Tobacco Product Package Type	Please Select
Describe Other Smokeless Tobacco Product Package Type	
Total Package Size or Weight for Smokeless Tobacco Product	
Flavor of Smokeless Tobacco Product	Please Select
Describe the Other Smokeless Tobacco Product Flavor(s)	

What is the country of manufacture of the study tobacco product? 20

Does the investigator still have access to the study tobacco product? 21

Yes  No  Unknown

Provide information about the times/dates of study tobacco product administration relative to the timing of the problem being reported. 22

ASC 

Manufacturer Name 23

Type to search and select

**Study Tobacco Product Manufacturer Information** 24

Manufacturer Name (Other)	
Country	Please Select
Phone	
Street Address Line 1	
Street Address Line 2	
City/Town	

# Tobacco Product Investigator's Report wireframes

## December 2015

State	Please Select	25
State/Province	<input type="text"/>	
ZIP/Postal Code	<input type="text"/>	
Web Address	<input type="text"/>	
Email Address	<input type="text"/>	

---

### Study Tobacco Product Use Details

How was the study tobacco product used? 25

- Inhaled (smoked or vaped)
- Puffed (not inhaled)
- Placed, rubbed, or swished in mouth
- Placed or sniffed/snorted in nose
- Swallowed
- Rubbed onto or applied to the skin
- Other

Describe other way the study tobacco product was used 26

On average, how often is this study tobacco product used? 27

Please Select

Are other substances being mixed in with the study tobacco product when used? 28

Yes  No  Unknown

Describe what substances are being mixed with the study tobacco product 28

Did the problem occur with first time use of the study tobacco product? 30

Yes  No

How long has the subject been using the study tobacco product? 31

Select Unit of Measure

Did the subject continue to use the study tobacco product? 32

Yes  No  Unknown

Were there any changes to the study tobacco product before use? (select all that apply) 33

- No
- Yes, protocol-specified changes were made by the manufacturer or research team
- Yes, the study subject made changes outside of the protocol and consent instructions
- Yes, other

Summarize the changes made to the study tobacco product by each and every entity 34

---

### Reaction and Study Tobacco Product Relatedness

In your opinion, how likely is it that the use of the study tobacco product is related to the health problem? 35

Please Select

Did this same or similar health problem happen again after repeat use of the study tobacco product? 36

Yes  No  N/A - Person did not restart use

Save 36 Cancel 37

# 11 Study Tobacco Product Part Details

**Study Tobacco Product Part Details**

Information and pictures to assist in identifying tobacco products can be found [here](#) 1

**Study Tobacco Product Part Type** 2  
Please Select

**Description of Other Study Tobacco Product Part Type** 3

**Full Study Tobacco Product Part Name, including Brand and Sub-Brand (if unknown, please enter "unknown")** 4

**In your opinion, how likely is it that the study tobacco product part is related to the problem?** 5  
Please Select

**When was the study tobacco product part purchased or acquired?** 6

**UNIVERSAL PRODUCT CODE (UPC) from Label** 7

**Any other identifying study tobacco product part codes (for example, SKU, item/catalog number, manufacturing date/batch code)** 8

**What is the country of manufacture of the study tobacco product part?** 9  
Please Select

**Do you know where the study tobacco product part was purchased?** 10  
 Yes  No  Product acquired by other means

**Study Tobacco Product Part Purchase Location** 11

**How was this study tobacco product part acquired?** 11  
Please Select

**Describe other acquisition source for study tobacco product part**

**Purchase Location Name**

**Country** 11  
Please select

**Phone**

**Street Address Line 1**

**Street Address Line 2**

**City/Town**

**State** 11  
Please select

**State/Province**

**ZIP/Postal Code**

**Web Address**

**Email Address**

**Do you know who manufactured this study tobacco product part?** 12  
 Yes  No

# Tobacco Product Investigator's Report wireframes December 2015

Manufacturer Name	<input type="text" value="Type to search and select"/>	13	
<b>Study Tobacco Product Part Manufacturer Information</b>			14
Manufacturer Name (Other)	<input type="text"/>		
Country	<input type="text" value="Please Select"/>		
Phone	<input type="text"/>		
Street Address Line 1	<input type="text"/>		
Street Address Line 2	<input type="text"/>		
City/Town	<input type="text"/>		
State	<input type="text" value="Please Select"/>		
State/Province	<input type="text"/>		
ZIP/Postal Code	<input type="text"/>		
Web Address	<input type="text"/>		
Email Address	<input type="text"/>		
	<input type="button" value="Save"/>	15	
	<input type="button" value="Cancel"/>	16	

# 12 Other Tobacco Products Used

The wireframe shows a web page titled "Safety Reporting Portal" with a navigation bar containing links for HOME, FAQs, RELATED LINKS, CONTACT US, FEEDBACK, HELP, and LOGOUT. The main content area is titled "Other Tobacco Products Used" and includes a "Required Field" indicator. The page contains several text blocks with numbered callouts (1-5) pointing to specific elements: 1 points to a note that the section is not used for certain study problems; 2 points to instructions on when to enter tobacco products; 3 points to a link for identifying products; 4 points to radio button options for nonstudy tobacco use; and 5 points to a table for listing products. The table has columns for "Nonstudy Tobacco Product Type", "Brand Name/Product Name", and "Current Use?". Below the table are "Add", "Edit", and "Delete" buttons. A footer contains navigation buttons (Save Draft, Exit, Submit Report, < Back, Next >) and a disclaimer.

Welcome User   HOME   FAQs   RELATED LINKS   CONTACT US   FEEDBACK   HELP   LOGOUT

Name: Tobacco Product Report (Research Study)  
ID: <ID>  
Created: <date>

**Other Tobacco Products Used**  
\* = Required Field

This section is not used when reporting on a study tobacco product problem without a health problem. **1**

Tobacco products used as part of the study, including those used in a baseline period of usual brand/product use and any contr... arm(s), should be entered in the Study Tobacco Products section. Tobacco products that were used prior to study enrollment or outside of the consent instructions should be entered here. **2**

Information and pictures to assist in identifying tobacco products can be found [here](#). **3**

Has the affected person used other nonstudy tobacco products (either currently or in the past)?  Yes  No  Unknown **4**

Select the Add button below if the person uses other tobacco products.

**Other Nonstudy Tobacco Products Used Currently or in the Past** **5**

Nonstudy Tobacco Product Type	Brand Name/Product Name	Current Use?
<input type="radio"/>		

Click on the Add button to add an item

        [**<** Page 1 of 1 **>**]

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

# 13 Other Tobacco Products Used Details

**Other Tobacco Products Used Details**

Information and pictures to assist in identifying tobacco products can be found [here](#)

**Nonstudy Tobacco Product Type**

- Cigarette
- Roll-your-own cigarette
- Bidis, Cloves, Herbal Cigarettes with tobacco
- Electronic cigarette, electronic nicotine or vaping product (E-cigarette, e-cigars, e-hookahs, e-pipes, vape pens, hookah pens, and personal vaporizers; E-liquids, e-juice or vape juice)
- Tobacco Heating System (heats tobacco leaf not liquid)
- Waterpipe (also known as hookah, narghile, shisha, or goza)
- Cigar (premium or large)
- Small Cigar, Little Cigar or Cigarillo
- Pipe or pipe tobacco
- Snuff (dry or moist for use in nose or mouth)
- Snus (pouches or loose)
- Chewing tobacco (loose leaf chew, plug, twist/roll)
- Gutka (or Gutkha), Betel Quid with Tobacco
- Mixture of tobacco with spices, herbs, nuts, fruit, plant leaves, etc. (used for chewing)
- Dissolvable (for example, strips, sticks, orbs)
- Nicotine Lotions or Gels (applied to the skin)
- Tobacco Powder, gel or paste applied to the teeth, gums, or mouth
- Other


**Description of other nonstudy tobacco product type**

**Nonstudy Tobacco Product Subtype**

**Description of other nonstudy tobacco product subtype**

**Full Nonstudy Tobacco Product Name including Brand and Sub-Brand (if unknown, please enter "unknown")**

Tobacco Product Investigator's Report wireframes  
December 2015

A  
B  
C 

**Is the nonstudy tobacco product currently being used?** 7

Yes (within the past 30 days)  
 No (more than 30 days ago)

**How is the nonstudy tobacco product used?** 8

Inhaled (smoked or vaped)  
 Puffed (not inhaled)  
 Placed, rubbed, or swished in mouth  
 Placed or sniffed/snorted in nose  
 Swallowed  
 Rubbed onto or applied to the skin  
 Other

**Describe how the nonstudy tobacco product is used** 9

**On average, how often is the nonstudy tobacco product used?** 10

11  12

# 14 Additional Information

**Safety Reporting Portal**

Welcome *User*   HOME   FAQs   RELATED LINKS   CONTACT US   FEEDBACK   HELP   LOGOUT

Name: Tobacco Product Report (Research Study)  
ID: <ID>  
Created: <date>

**Additional Information**

Please describe anything else you think the FDA should know about this problem. Attachments may be added on the next page. **1**

Introduction  
Contact Information  
Problem Summary  
Research Summary  
Study Tobacco Products  
Other Tobacco Products Used  
Additional Information  
Attachments

My Report History  
OMB Approval Number:  
<OMB Approval #>  
OMB Expiration Date:  
<date>  
OMB Burden Statement

Save Draft   Exit   Submit Report   < Back   Next >

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]



# 15 Attachments

Welcome User   HOME   FAQs   RELATED LINKS   CONTACT US   FEEDBACK   HELP   LOGOUT

Name: Tobacco Product Report (Research Study)  
ID: <ID>  
Created: <date>

**Attachments** 1

\* = Required Field

Please attach pictures of the product and any other supporting documentation. 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.  
Audio and video files cannot be uploaded.

File Name	Type	Description
<input type="text"/>		Click on the Add button to add an item

        [[< Page 1 of 1 >](#)]

My Report History  
OMB Approval Number:  
<OMB Approval #>  
OMB Expiration Date:  
<date>  
OMB Burden Statement

[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

# 16 Attach File

**Attach File**

NOTE: when specifying files to attach to the report, the following restrictions apply:

1. the file path, including file name and folders, may not exceed 250 characters;
2. the file name may not exceed 217 characters.

**File to Attach**  **1**  **4**

**Description of Attachment**  **2**

**Type of Attachment**  **3**

**5**  **6**