

Tobacco Product Report v2 Wireframes December 2015

1 My Reports - TPR

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Safety Reporting Portal

My Report History

Select Group 30

TPR Proxy

My Account

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My Reports

Group ID: <Group ID> 1

<Reporter Role> 2

Member: Self 3

Draft Reports 4

Click column header to sort the column

Date Saved (EST) 5	Report ID 6	Title 7	Report Type Description 8
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (i)	<Title provided by user>	<Defined report name- Created By: <Reporter name>
Start New Report 9	Edit 10	Delete 11	View 12 Refresh List 13

Please make sure an appropriate group is selected from the left navigation menu before creating a report. 32

Submitted Reports Available for Follow-Up 14

Submitted as of (mm/dd/yyyy or mm/yyyy): ICSR Number (please enter the number only): Title: 17

Member: Self 20

Click column header to sort the column

Date Submitted (EST) 24	Report ID 22	ICSR# 23	Title 24	Report Type Description 25
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (i)	<ICSR number> (i)	<Title provided by user>	<Defined report name- Submitted By: <Reporter name>
<MM/DD/YYYY HH:MM:SS AM>	<report ID> (F)	<ICSR number> (i)	<Title provided by user>	<Defined report name- Canceled By: <Reporter name>
Start Follow-up Report 26	View 27	View PDF 28	Refresh List 29	< <Page 1 of 1 >

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3 My Account -TPR

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

Safety Reporting Portal

My Report History

My Account

My Groups

My Account

*** = Required**

Reporter Information

[Change Password and Security Question](#)

* Reporter Role

* First Name

* Last Name

Job Title

Healthcare Professional Type

Consumer/Concerned Citizen Type (select all that apply)

Consumer Distributor
 Concerned citizen Wholesaler
 Retailer Supplier
 Importer Other

Describe other healthcare professional type

Describe other consumer/concerned citizen type

* Email Address (this will be your Login ID)

* Primary Phone

Other Phone

Fax

Primary Phone - country code

Primary Phone - number/extension

Reporter Address

Organization Name

* Country

* Street Address Line 1

Street Address Line 2

* City/Town

* State

State/Province

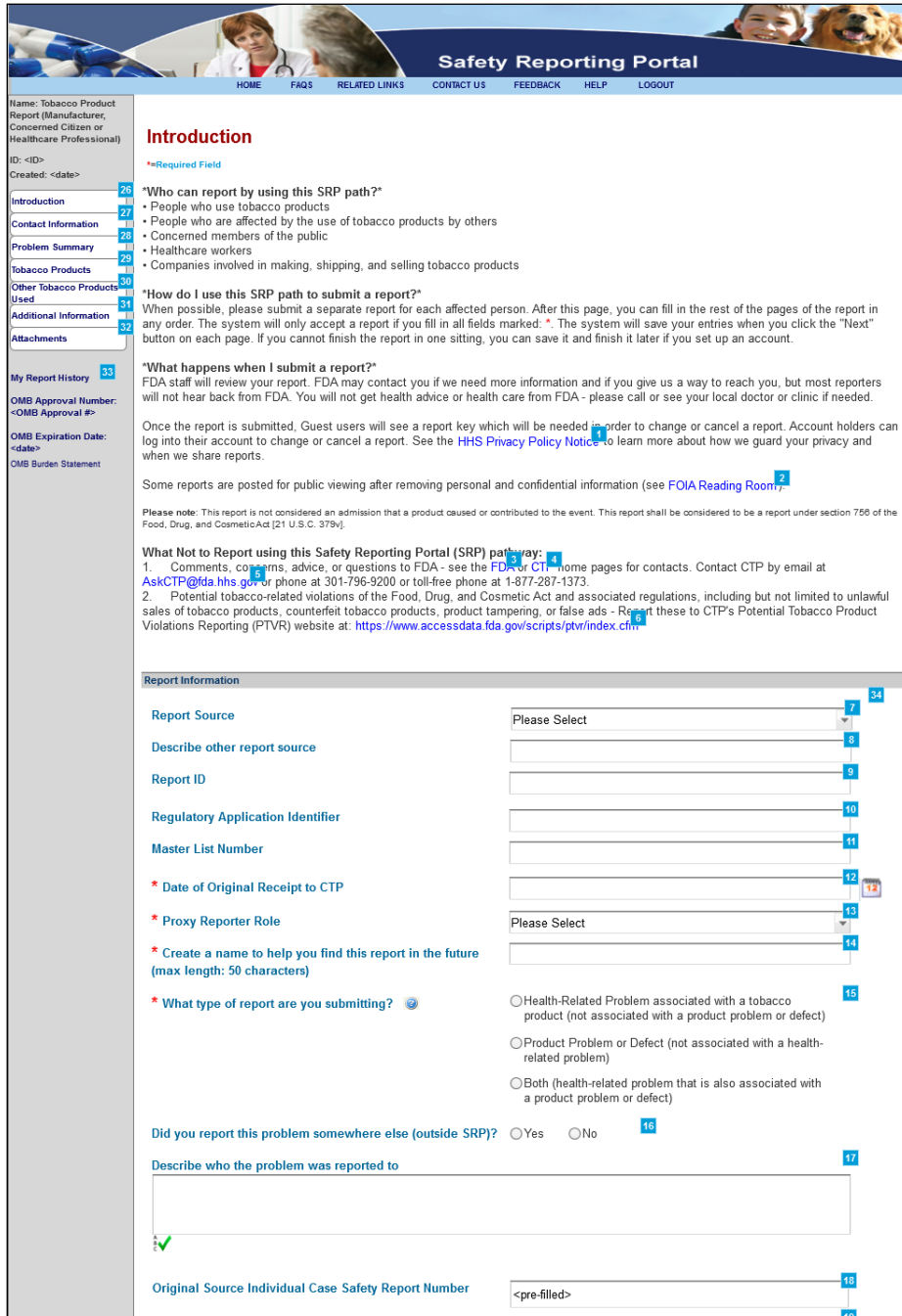
* ZIP/Postal Code

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

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4 Introduction - TPR



The wireframe shows the 'Introduction' page of the Safety Reporting Portal. At the top, there is a navigation bar with links for HOME, FAQs, RELATED LINKS, CONTACT US, FEEDBACK, HELP, and LOGOUT. Below the navigation bar is a header area with the title 'Safety Reporting Portal' and a decorative image of a doctor and a dog. The main content area is titled 'Introduction' and contains several sections of text and links. On the left side, there is a sidebar with a table of contents and a 'My Report History' section. The 'Report Information' section is a form with various fields and options, including 'Report Source', 'Report ID', 'Regulatory Application Identifier', 'Master List Number', 'Date of Original Receipt to CTP', 'Proxy Reporter Role', 'Create a name to help you find this report in the future', 'What type of report are you submitting?', 'Did you report this problem somewhere else (outside SRP)?', 'Describe who the problem was reported to', and 'Original Source Individual Case Safety Report Number'.

Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)
ID: <ID>
Created: <date>

Introduction

***Required Field**

Who can report by using this SRP path?

- People who use tobacco products
- People who are affected by the use of tobacco products by others
- Concerned members of the public
- Healthcare workers
- Companies involved in making, shipping, and selling tobacco products

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.

Once the report is submitted, Guest users will see a report key which will be needed in order to change or cancel a report. 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. 379).

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

1. 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 or phone at 301-796-9200 or toll-free phone at 1-877-287-1373.
2. 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 Please Select

Describe other report source

Report ID

Regulatory Application Identifier

Master List Number

*** Date of Original Receipt to CTP**

*** Proxy Reporter Role** Please Select

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

*** What type of report are you submitting? ***

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)

Did you report this problem somewhere else (outside SRP)? Yes No


Describe who the problem was reported to

Original Source Individual Case Safety Report Number <pre-filled>

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Original Submission Date	<pre-filled>		
Follow-Up Reason(s) (select all that apply)	<input type="checkbox"/> Additional Information <input type="checkbox"/> Correction <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Cancel Submitted Report (the system has compiled the original report and its follow-up reports (if any) into a single report) <input type="checkbox"/> Reactivate Canceled Report <input type="checkbox"/> Other		
Are you sure you want to cancel the previous report?	<input type="radio"/> Yes <input type="radio"/> No		
Describe the reason for canceling the report			
Describe the other reason for submitting this follow-up report			
Summarize reason for reactivating the canceled report			
Additional notes about this report:			
Save Draft	Exit	Submit Report	Next

5 Contact Information - TPR



Welcome User HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)

ID: <ID>

Created: <date>

Introduction

Contact Information

Problem Summary

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.

For registered users, 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 1

Last Name 2

May the FDA share your name and contact information with the manufacturer/distributor of the tobacco product(s) described in your report? Yes No 3

May the FDA share your name and contact information with other federal government agencies (e.g. CDC, CPSC, FTC, TTB)? Yes No 4

May the FDA share your name and contact information with local or state government agencies (e.g. enforcement or public health/safety agencies)? Yes No 5

Did you report the problem to the manufacturer? Yes No 6

Email
(If prefilled, changing this email address will not change your Login email ID)

Confirm Email

7

8

Country 9

Phone 10

Street Address Line 1 11

Street Address Line 2 12

City/Town 13

State 14

State/Province 15

Zip/Postal Code 16

*** Sender Category** 17

Organization Name 18

Job Title 19

Healthcare Professional Type 20

Consumer/Concerned Citizen Type (select all that apply)

Consumer 21

Concerned citizen

Retailer

Importer

Distributor

Wholesaler

Supplier

Other 22

Describe other healthcare professional type 23


Describe other consumer/concerned citizen type 24

Are you the person who experienced health problems associated with a tobacco product? Yes No 24

Describe your relationship to the person who experienced the health problem 25

Save Draft
Exit
Submit Report
Next

6 Problem Summary


Safety Reporting Portal

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Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)
ID: <ID>
Created: <date>

Introduction

Contact Information

Problem Summary

Tobacco Products

Other Tobacco Products Used

Additional Information

Attachments

My Report History

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

Problem Summary

Affected Person

Affected Person 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

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

7

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Describe the other product problem 14

A
S
C ✓

What are the main symptoms or health problems? 15

MedDRA Term

Click on the Add button to add an item

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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

A
S
C ✓

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

A
S
C ✓

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

A
S
C ✓

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

Yes No

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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."

Term describing the health problem 1

2 3

8 Tobacco Products


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Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)

ID: <ID>

Created: <date>

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

My Report History

OMB Approval Number:
<OMB Approval #>

OMB Expiration Date:
<date>

OMB Burden Statement

Tobacco Products

*** = Required Field**

"Use the "Add" button in the table below to enter information for each tobacco product that may have caused the health problem or product problem. Information and pictures to assist in identifying tobacco products can be found [here](#) 1

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.

*** Tobacco Product(s)** 2

Product Type	Product Subtype	Brand Name/Product Name
<input type="radio"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" 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 >|

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. 4

Tobacco Product Part(s) for <Product Type> 3

Product Part Type	Product Part Name	Purchase Location	Manufacturer
<input type="radio"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" type="text"/>	<input style="width: 95%;" 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"/>	

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9 Tobacco Product Details

Tobacco Product Details

Enter information about a single 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 products that may have caused the health or product problem.

Information and pictures to assist in identifying tobacco products can be found [here](#) 44

*** Tobacco Product Type** 1

- 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

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

Description of other tobacco product type 2

Tobacco Product Subtype 3

Please Select

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

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A
B
C ✓

Describe other cigar type 5

Describe homemade electronic vaporizer device 6

A
B
C ✓

Describe other snuff type 7

Describe other snus type 8

Describe other dissolvable product subtype 9

Describe other chewing tobacco subtype 10

11

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

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

A
B
C ✓

What does the electronic or battery powered hookah/shisha/waterpipe look like? Please Select

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

A
B
C ✓

The tobacco or shisha product used was 12

A Premixed Preparation

Custom Mixed or Mixed to Order

Mixed or Modified by User

Describe the tobacco or shisha mix

A
B
C ✓

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

A
B
C ✓

Select all that apply to the electronic cigarette, electronic nicotine or vaping product (including electronic waterpipe) 13

Disposable (non-refillable) product

Rechargeable product

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<p>How has the electronic cigarette, electronic nicotine or vaping product been modified by the user? (select all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Uses prefilled cartridge, cart, cartomizers or carto. <input type="checkbox"/> Uses refillable cartridge, cart, cartomizers or carto (that are filled by the user) <input type="checkbox"/> Uses a Tank or Tank System <input type="checkbox"/> Modified: the original product was modified <input type="checkbox"/> Power (watts) can be changed or adjusted <input type="checkbox"/> Voltage can be changed or adjusted <input type="checkbox"/> Button activated <input type="checkbox"/> Puff/flow activated <input type="checkbox"/> The battery or power source has been changed <input type="checkbox"/> The heating element or atomizer has been changed <input type="checkbox"/> The tank system has been changed <input type="checkbox"/> Other
<p>Describe other electronic cigarette, electronic nicotine or vaping product modification</p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div>	
<p>Select all that apply to the e-liquid, e-juice or vape juice for your electronic cigarette, electronic nicotine or vaping product</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Purchased in a non-refillable disposable cartridge <input type="checkbox"/> Purchased for use in a capsule, tank or refillable cartridge <input type="checkbox"/> Mixed in a shop or on-line per request or "to order" <input type="checkbox"/> Mixed or modified by the user
<p>Describe the e-liquid mix</p> <div style="border: 1px solid black; height: 25px; width: 100%;"></div>	
<p>Does the e-liquid, e-juice or vape juice contain any of the following? (select all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Nicotine <input type="checkbox"/> Coloring Agents <input type="checkbox"/> Flavor(s) <input type="checkbox"/> Glycerin <input type="checkbox"/> Propylene Glycol <input type="checkbox"/> Water <input type="checkbox"/> Other
<p>Describe other e-liquid ingredients</p> <div style="border: 1px solid black; height: 15px; width: 100%;"></div>	
<p>What type(s) of flavor(s) does the e-liquid contain? (select all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Tobacco <input type="checkbox"/> Menthol <input type="checkbox"/> Mint (such as wintergreen or spearmint) <input type="checkbox"/> Clove or Spice <input type="checkbox"/> Fruit

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<p>Describe other e-liquid flavor(s)</p> <p>Was the e-liquid dripped on to the atomizer or heating element?</p> <p>* Full Tobacco Product Name, including Brand and Sub-Brand (if unknown, please enter "unknown")</p> <p>When did the person purchase this product?</p> <p>UNIVERSAL PRODUCT CODE (UPC) from Label</p> <p>Any other identifying tobacco product codes (for example, SKU, item/catalog number, manufacturing date/batch code)</p>	<p> <input type="checkbox"/> Fruit <input type="checkbox"/> Candy or Chocolate <input type="checkbox"/> Alcoholic Drink <input type="checkbox"/> Combination/Mixture of Flavors <input type="checkbox"/> Other </p> <p> <input type="text"/> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown </p> <p><input type="text"/></p> <p><input type="text"/></p> <p><input type="text"/></p> <p><input type="text"/></p> <p><input type="text"/></p>
15	
16	
17	
18	
19	
20	


Tobacco Product Packaging and Portions

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

Cigarette Length	Please Select
Describe Other Cigarette Length	<input type="text"/>
Cigarette Size/Diameter	Please Select
Describe Other Cigarette Size/Diameter	<input type="text"/>
Package Size/# of Cigarettes per Pack	Please Select
Describe Other Cigarette Package Size	<input type="text"/>
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")	<input type="text"/>
Smokeless Tobacco Product Package Type	Please Select
Describe Other Smokeless Tobacco Product Package Type	<input type="text"/>
Total Package Size or Weight for Smokeless Tobacco Product	<input type="text"/>
Flavor of Smokeless Tobacco Product	Please Select



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Describe the Other Smokeless Tobacco Product Flavor(s)

What is the country of manufacture of the tobacco product?  21



Where is the tobacco product now? 22

Manufacturer Investigation Information 23



On what date did you first become aware of the problem?  

What information source prompted this report? (Select all that apply) Internal Quality Control/Quality Assurance (QC/QA) Consumer Report Other

Provide reporter contact information if available



 

Describe other information source

Are you aware of any similar or related reports? Yes No

Describe the related reports. List the ICSR numbers if available. Submit related reports individually.

Have there been any manufacturing changes, or are you aware of any manufacturing or quality problems for this product that are relevant to this report? Yes No

Describe the manufacturing issues. Additional information can be added as attachments to the report.

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A
P
C ✓

Are you conducting or have you conducted any investigation into this report? Yes No

Please explain, and include manufacturing code information.

A
P
C ✓

Have you made any effort to correct the condition/issue or remove the product from the market? Yes No

Describe and provide specifics, including documentation as attachments at the end of this report.

A
P
C ✓

What is the marketing status of the tobacco product in the United States?

Provide FDA-assigned tracking number(s) (STN), if applicable

Describe other regulatory status

A
P
C ✓


Is this report related to a health problem occurring during an investigational study? Yes No

Was this health problem reported to the Safety Reporting Portal by the investigator? Yes No Unknown

Provide ICSR number and/or date of the report

Provide investigator contact information

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How was this product acquired? 24

If other, please describe 25

Do you know where the tobacco product was purchased? Yes No 26

Tobacco Product Purchase Location 27

Purchase Location Name

Country

Phone

Street Address Line 1

Street Address Line 2

City/Town

State

State/Province

ZIP/Postal Code

Web Address

Email Address

Manufacturer Name 28

Tobacco Product Manufacturer Information 29

Manufacturer Name (Other)

Country

Phone

Street Address Line 1

Street Address Line 2

City/Town

State

State/Province

ZIP/Postal Code

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Web Address	<input type="text"/>
Email Address	<input type="text"/>
Tobacco Product Use Details	
How was the tobacco product used?	<input type="checkbox"/> Inhaled (smoked or vaped) 30 <input type="checkbox"/> Puffed (not inhaled) <input type="checkbox"/> Placed, rubbed, or swished in mouth <input type="checkbox"/> Placed or sniffed/snorted in nose <input type="checkbox"/> Swallowed <input type="checkbox"/> Rubbed onto or applied to the skin <input type="checkbox"/> Other
Describe other way the tobacco product was used	<input type="text"/> 31
On average, how often is this tobacco product used?	Please Select 32
Are other substances being mixed in with the tobacco product when used?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown 33
Describe what substances are being mixed with the tobacco product	<input type="text"/> 34
Did the problem occur with first time use of this tobacco product?	<input type="radio"/> Yes <input type="radio"/> No 35
How long has the person been using this type of tobacco product?	<input type="text"/> Select Unit of Measure 36
How soon after the tobacco product was last used did the health problem occur?	<input type="text"/> Select Unit of Measure 37
How long has the person been using this particular brand or label?	<input type="text"/> Select Unit of Measure 38
Do you think this problem was caused by a particular package or unit of this product?	<input type="radio"/> Yes <input type="radio"/> No 39
Did the person continue to use this tobacco product after the problem occurred?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown 40
Did this same or similar health problem happen again after repeat use of the tobacco product?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A - Person did not restart use 41
Did the person change the product in any way before using it (for example, removing a filter from a cigarette)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown 42
Please explain how the product was changed prior to its use	<input type="text"/> 43
<input type="button" value="Save"/> 45 <input type="button" value="Cancel"/> 46	

10 Tobacco Product Part Details

Tobacco Product Part Details

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

Tobacco Product Part Type 2

Description of Other Tobacco Product Part Type 3

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

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

When was this tobacco product part purchased or acquired? 6

UNIVERSAL PRODUCT CODE (UPC) from Label 7

Any other identifying tobacco product part codes(e.g. SKU, item/catalog number) 8

What is the country of manufacture of the tobacco product part? 9

Where is the tobacco product part now? 10

Tobacco Product Part Purchase Location

How was this tobacco product part acquired? 11

Describe other acquisition source for the tobacco product part 12

Purchase Location Name 13

Country 14

Phone 15

Street Address Line 1 16

Street Address Line 2 17

City/Town 18

State 19

State/Province 20

ZIP/Postal Code 21

Web Address 22

Email Address 23

Are you the manufacturer of this tobacco product part? Yes No 24

Do you know who manufactured this tobacco product part? Yes No 25

Manufacturer Name 26

Tobacco Product Part Manufacturer Information

Manufacturer Name (Other) 27

Tobacco Product Report v2 Wireframes December 2015

Manufacturer Name (Country)	<input type="text"/>
Country	Please Select <input type="button" value="v"/>
Phone	<input type="text"/>
Street Address Line 1	<input type="text"/>
Street Address Line 2	<input type="text"/>
City/Town	<input type="text"/>
State	Please Select <input type="button" value="v"/>
State/Province	<input type="text"/>
ZIP/Postal Code	<input type="text"/>
Web Address	<input type="text"/>
Email Address	<input type="text"/>

Save Cancel

11 Other Tobacco Products Used

The wireframe shows a web page titled "Safety Reporting Portal" with a navigation bar containing "HOME", "FAQS", "RELATED LINKS", "CONTACT US", "FEEDBACK", "HELP", and "LOGOUT". The main content area is titled "Other Tobacco Products Used" and includes a warning: "This section is not used when reporting on a tobacco product problem without a health problem." Below this, there is a link "here" and a question: "Has the affected person used other tobacco products (either currently or in the past)?" with radio buttons for "Yes", "No", and "Unknown". A section titled "Other Tobacco Products Used Currently or in the Past" contains a table with columns "Product Type", "Brand Name/Product Name", and "Current Use?". Below the table are "Add", "Edit", and "Delete" buttons, and a page indicator "<Page 1 of 1 >". A footer bar contains "Save Draft", "Exit", "Submit Report", "< Back", and "Next >" buttons. At the bottom, there are links for "PRIVACY POLICY", "FREEDOM OF INFORMATION ACT", "ACCESSIBILITY", and "DISCLAIMER", along with a 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.]"

Welcome User

HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)
ID: <ID>
Created: <date>

Other Tobacco Products Used

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

Information and pictures to assist in identifying tobacco products can be found [here](#) 2

Has the affected person used other tobacco products (either currently or in the past)? Yes No Unknown 3

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

Other Tobacco Products Used Currently or in the Past 4

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

Click on the Add button to add an item

Add Edit Delete |< Page 1 of 1 >

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.]

12 Other Tobacco Products Used Details

Other Tobacco Products Used Details

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

Tobacco Product Type

- Cigarette 2
- 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 tobacco product type 3

Tobacco Product Subtype 4

Please Select

Description of other tobacco product subtype 5

Full Tobacco Product Name including Brand and Sub-Brand
(if unknown, please enter "unknown") 6

A

Tobacco Product Report v2 Wireframes December 2015

Is the tobacco product currently being used? 7

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

How is the 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 tobacco product is used 9

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

Please Select

11 12

13 Additional Information

Safety Reporting Portal

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

Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)
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
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](#)

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14 Attachments



The wireframe shows a web page for the 'Safety Reporting Portal'. At the top, there is a header with navigation links: HOME, FAQs, RELATED LINKS, CONTACT US, FEEDBACK, HELP, and LOGOUT. Below the header is a sidebar on the left with a list of menu items: Introduction, Contact Information, Problem Summary, Tobacco Products, Other Tobacco Products Used, Additional Information, Attachments, My Report History, OMB Approval Number, OMB Expiration Date, and OMB Burden Statement. The main content area is titled 'Attachments' and includes a sub-header '* = Required File'. A text box provides instructions: '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.' Below this is a table with columns for 'File Name', 'Type', and 'Description'. The table is currently empty, and a message says 'Click on the Add button to add an item'. At the bottom of the table are buttons for 'Add', 'Edit', and 'Delete', along with a page indicator '< Page 1 of 1 >'. At the very bottom of the page are buttons for 'Save Draft', 'Exit', 'Submit Report', '< Back', and 'Next >', and a footer with links for 'PRIVACY POLICY', 'FREEDOM OF INFORMATION ACT', 'ACCESSIBILITY', and 'DISCLAIMER'. A small disclaimer at the bottom reads: '[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 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