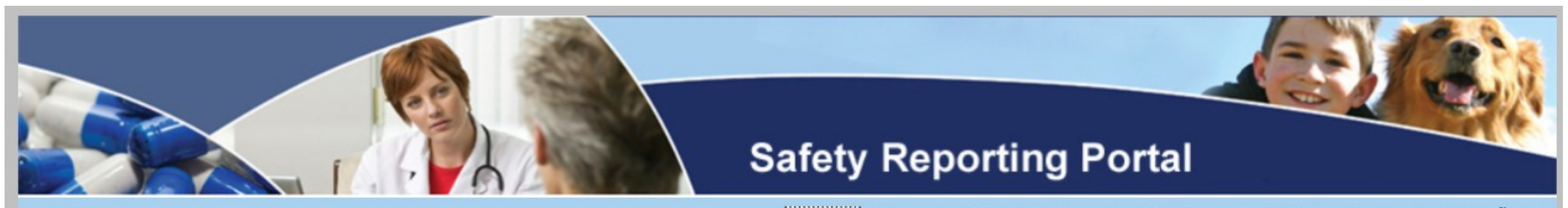

Name: Tobacco Product Report (Manufacturer, Concerned Citizen or Healthcare Professional)

ID: FPSR15654 (I)

Created: 10/18/2018

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

OMB Approval Number: 0910-0645

OMB Expiration Date: 05/31/2019

OMB Burden Statement

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. 379v].

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.

Remove the word "-related" throughout (for example, "Health-related Problem" becomes "Health Problem"

Report Information

***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

Exit | Submit Report | Next >

[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.]

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

ID: FPSR15655 (I)

Created: 10/18/2018

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

OMB Approval Number: 0910-0645

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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

Last Name

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

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

Remove these three questions

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

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

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

Confirm Email

Country Please select

Phone

Street Address Line 1

Street Address Line 2

City/Town

State Please select

ZIP/Postal Code

***Sender Category** Healthcare Professional (FdaTPR)

Organization Name

Job Title

Healthcare Professional type Please select

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

Changing "Health care Professional Type" list of values

FROM:
Physician
Physician Assistant
Nurse Practitioner
Nurse
Pharmacist
Other

TO:
Physician
Physician Assistant
Nurse Practitioner
Nurse
Pharmacist
Emergency Medical Technician (EMT)
Firefighter
Fire Investigator
Fire Marshal
Other Public Health Professional
Other

Exit | Submit Report | < Back | Next >

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

ID: FPSR15655 (I)

Created: 10/18/2018

OMB Approval Number: 0910-0645

OMB Expiration Date: 05/31/2019

OMB Burden Statement

Problem Summary

*=Required Field

Affected Person

Affected Person Identifier Code

Gender ○ Male ○ Female

Add selection "Other"

Ethnicity

○ Hispanic or Latino
○ Not Hispanic or Latino
○ Unknown

Insert question: "How many users were affected?"

Race (Select all that apply)

☐ American Indian or Alaskan Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Unknown

Requested to add "Other" -- OMB will NOT approve this change

Birth date of the person who experienced the health problem

For the following field, enter a number in the first field, fol... by a Unit of Age from the dropdown field. If the affected person was an unborn child, select "unborn child" from ... and leave the number field blank.

When a Unit of Age other than "unborn child" is selected ... 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.

Remove the word "health"

Age of the person when the problem occurred Select Unit of Age

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.**

Request changing this list of values TO this one

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

☐ Appearance, look, smell, or taste issue
☐ Child safety hazard
☐ Damaged, broken or defective product, part, accessory, or package
☐ Exploded, caught on fire, or burned abnormally
☐ Foreign material (something in the product that does not belong)
☐ Hard to open or to use
☐ Label or instruction issue
☐ Leaked or spilled
☐ Overheated
☐ Product failed or did not work correctly
☐ Wrong number of items in package
☐ Wrong product in package
☐ Other

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

☐ Appearance or look issue
☐ Child safety hazard
☐ Smell issue
☐ Hard to open
☐ Taste issue
☐ Hard to use
☐ Damaged, broken, or defective product
☐ Leaked
☐ Damaged, broken or defective part
☐ Spilled
☐ Damaged, broken or defective accessory
☑ Overheated
☐ Damaged, broken or defective package
☐ Exploded
☐ Label issue
☐ Caught on fire when it wasn't supposed to
☐ Instruction issue
☐ Burned abnormally after being lit
☐ Wrong number of items in package
☐ Product failed or did not work correctly (not involving overheating, fire, exp or abnormal burning)
☐ Wrong product in package
☐ Other

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

Term describing the health problem
Click on the **Add** button to add an item

Add | Edit | Delete

At least one health problem must be reported.

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

☐ Death
☐ Lasting disability or ot
☐ Life threatening
☐ Birth defect
☐ Hospitalization (overnight or longer)
☐ Needed treatment to prevent permanent harm
☐ Emergency room visit without hospital admission
☐ Other serious medical event
☐ None of the above

Change "Birth defect" to "Adverse pregnancy outcome including birth defects"

Remove "Emergency Room visit without hospitalization" option from this list

Treatment Received (select all that apply)

☐ None
☐ Healthcare Professional Visit
☐ Self-Treated
☐ Other

Add new question below "Treatment Received"

Add selection option of "Emergency room visit without hospital admission"

***In what setting(s) did this problem occur? (select all that apply)**

☐ One person using one or more product(s)
☐ Two or more people sharing the use of one or more product(s)
☑ In the place where I live
☐ Public indoor location (office, store, mall, restaurant, bar, school, sports arena)
☐ Public outdoor location (park, stadium, hiking trail)
☐ Near medical oxygen
☐ Moving car
☐ Parked car
☐ Bus/subway/train
☐ Airplane/helicopter
☐ Boat
☐ Unknown
☐ Other

Name: Tobacco Product Report (Research Study) Created by: test345 last

ID: FPSR15660 (I)

Created: 10/18/2018

OMB Approval Number: 0910-0645

OMB Expiration Date: 05/31/2019

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)

Tracking Number Type	Tracking Number	STN
Click on th		

Add Edit Delete

Request to make the "FDA-Assigned Protocol number" a required field. This ONLY applies to Clinical Investigators submitting reports to FDA, not the general consumer

FDA-assigned Protocol Number

***Study Name and/or Identifier**

test

***Study Sponsor Name(s)**

test

Name of Principal Investigator

Clinical Trial Site where problem occurred or was discovered

Institutional Review Board (IRB) Name

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

- ☐ Data Safety Monitoring Board (DSMB)
- ☐ Institutional Review Board (IRB)
- ☐ Product manufacturer
- ☐ Study Sponsor
- ☐ Other

Request changing the question above ("Select the entities...", parsed out into the 3 questions below

***Have you notified the Data Safety Monitoring Board (DSMB)?**

- ◉ Yes
- ○ No, Plan to notify
- ○ No, Study does not have a DSMB
- ○ No, Per protocol
- ○ No, Other

***Have you notified the Institutional Review Board (IRB)?**

- ◉ Yes
- ○ No, Plan to notify
- ○ No, Study does not have a IRB
- ○ No, Per protocol
- ○ No, Other

Select any other entities that have been notified of this problem (select all that apply)

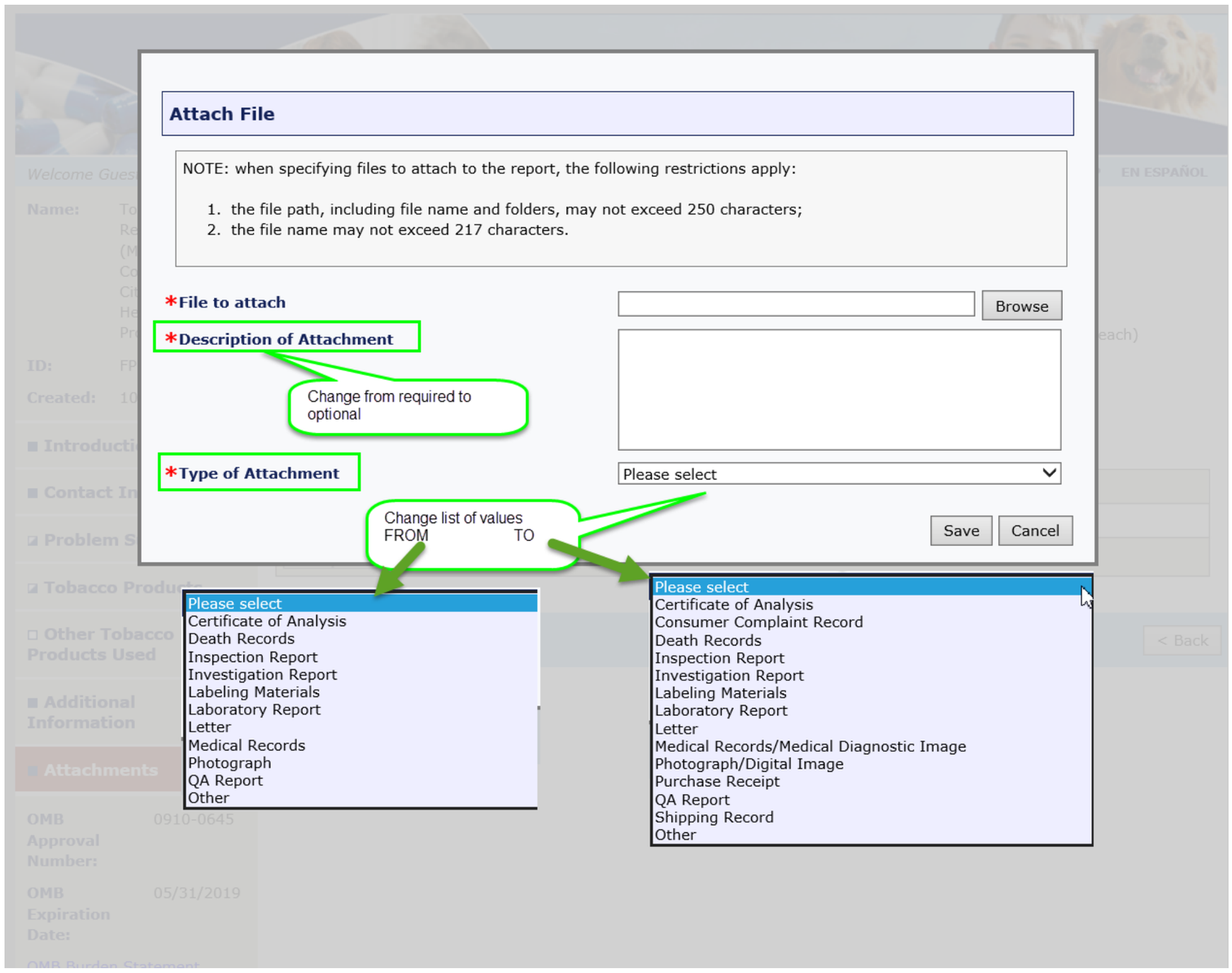
- ☐ NIDA SAETRS
- ☐ Study Sponsor
- ☐ Product Manufacturer
- ☐ No entity notified
- ☐ Other

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.

Save Draft Exit Submit Report < Back Next >


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
Browse
*Description of Attachment
Change from required to optional
*Type of Attachment
Please select
Change list of values
FROM
TO
Save
Cancel
Please select
Certificate of Analysis
Death Records
Inspection Report
Investigation Report
Labeling Materials
Laboratory Report
Letter
Medical Records
Photograph
QA Report
Other
Please select
Certificate of Analysis
Consumer Complaint Record
Death Records
Inspection Report
Investigation Report
Labeling Materials
Laboratory Report
Letter
Medical Records/Medical Diagnostic Image
Photograph/Digital Image
Purchase Receipt
QA Report
Shipping Record
Other
EN ESPAÑOL
< Back
OMB Number:
OMB Expiration Date:
05/31/2019