

CENTER FOR TOBACCO
PRODUCTS

OFFICE OF SMALL BUSINESS
ASSISTANCE

HOW TO REPORT A POTENTIAL
TOBACCO PRODUCT VIOLATION
OR AN ADVERSE EXPERIENCE
RELATED TO A TOBACCO
PRODUCT

The FDA logo is a blue square with the letters "FDA" in white, sans-serif font.

AGENDA

- How to report the right information to the right system in the Center for Tobacco Products
- What is a potential tobacco product violation?
- Four ways to report a potential tobacco violation
 - Online
 - E-mail electronic Form FDA 3779
 - Telephone
 - Post mail
- Report an adverse experience related to a tobacco product using the FDA's Safety Reporting Portal



WHAT IS A POTENTIAL TOBACCO PRODUCT VIOLATION?



If you see what you believe to be a violation of the Tobacco Control Act or other related regulations, you can submit a Potential Tobacco Product Violation report to the FDA Office of Compliance and Enforcement.

What are examples of Potential Tobacco Products Violations:

- Sale of single cigarettes
- Sales of tobacco to an underage purchaser (under age 21)
- Sale of flavored tobacco products
- Sale of tobacco products through vending machines and self-service displays, except in adult-only facilities
- Illegal marketing and advertising of tobacco products
 - Describing tobacco products as “light,” “mild,” or “low” – or claiming a product is safer or less harmful without an FDA order
 - Distributing t-shirts or other promotional or novelty items with brand names of cigarette or smokeless tobacco products
 - Sponsoring events using the brand name of a tobacco product

HOW TO REPORT A POTENTIAL TOBACCO PRODUCT VIOLATION - ONLINE

USING FORM FDA 3779 FOR REPORTING ONLINE



To report what you believe to be a potential tobacco product violation of the Tobacco Control Act or other related regulations:

- Online submission of FORM FDA 3779 at <https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>
- Accessibility and Language options
- Instruction on how to view files of different formats

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System

Potential Tobacco Product Violations Reporting - Form FDA 3779

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

[Paperwork Reduction Act Statement](#)

How to Report Potential Violations

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products, Office of Compliance and Enforcement.

Report a potential tobacco violation:

[Report Online](#)

To submit a report, use the "Report Online" button above to link to the web form or choose one of the following options:

[email](#) [phone](#) [mail](#)

WHO can report? -- Any member of the public.

Tell us:

WHEN did you see the potential violation?

WHERE did the potential violation occur?

WHAT is the potential violation?

WHY report? -- Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

All reports will remain private to the extent allowed by law. For more information please visit [FDA's Internet policies](#).

Children's Privacy: We collect no information from children under 13. If a child sends us an email inquiry or comment, we will answer it, and then delete the email from our files.

Page Last Updated: 01/09/2020
Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Пycкoвский | العربية | Kreyol Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

ONLINE FORM FDA 3779 – INITIAL PAGE



POTENTIAL TOBACCO PRODUCT VIOLATION REPORTING FORM FDA 3779

Home page:

<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>

Click **Report Online** box to continue

The screenshot shows the initial page of the Potential Tobacco Product Violations Reporting System (PTVR). At the top, it features the U.S. Department of Health and Human Services logo and the U.S. Food & Drug Administration logo. A search bar is located in the top right corner. Below the navigation menu, the breadcrumb trail reads: Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System. The main heading is "Potential Tobacco Product Violations Reporting - Form FDA 3779". Social media sharing options (Share, Tweet, LinkedIn, Pin It, Email, Print) are provided. A link to the "Paperwork Reduction Act Statement" is also present. The section "How to Report Potential Violations" explains that the form is used to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. A central box titled "Report a potential tobacco violation:" contains a red arrow pointing to a blue "Report Online" button. Below this, it states: "To submit a report, use the 'Report Online' button above to link to the web form or choose one of the following options:" followed by three buttons: "email", "phone", and "mail". The page also includes sections for "WHO can report?" (Any member of the public), "WHEN did you see the potential violation?", "WHERE did the potential violation occur?", and "WHAT is the potential violation?". A "WHY report?" section explains that public information is helpful in identifying problems with marketed products. A "Children's Privacy" notice states that no information is collected from children under 13. The footer includes the page last updated date (01/09/2020) and a note about language assistance available in multiple languages.

ONLINE FORM FDA 3779 – PAGE 1 – POTENTIAL VIOLATION



POTENTIAL TOBACCO PRODUCT VIOLATION REPORTING

- Date the potential violation occurred
- State where the potential violation occurred
- Tobacco product type
- Tobacco product name
- Potential tobacco product violation type
- Description of potential tobacco product violation, and
- Option for attaching files related to the potential tobacco product violation

U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System

Potential Tobacco Product Violations Reporting - Form FDA 3779

1 2 3 4
Potential Violation Information Who Potentially Violated Contact Information Review and Submit

Potential Violation Information
*** Required field**

Date Potential Violation Occurred *
mm/dd/yyyy
 I do not recall the date this potential violation occurred.

State Potential Violation Occurred *
--

Product Type *
--

Tobacco Product Name (200 character limit)

Potential Violation Type * (Check all that apply)

Sales to minors
 Flavored cigarette sales
 Advertising/Labeling/Promotion/Marketing
 Free samples
 Sales of cigarettes in packs less than 20

Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products
 Self-service display/direct access to cigarette or smokeless tobacco
 Unsure

Description of Potential Violation (4000 character limit)

Upload Relevant Files
Allowed combined size of all the files is 15 MB.
You may select multiple files by holding the Ctrl key and selecting the files you wish to upload.

Acceptable File Formats

Select Files Begin Upload

File Upload Queue Size: 0k

If you are having difficulty uploading files, use our accessible [file uploader](#).

Uploaded files:
No files uploaded. Ok

Next

ONLINE FORM FDA 3779 – PAGE 2 – POTENTIAL VIOLATOR



POTENTIAL TOBACCO PRODUCT VIOLATION REPORTING

WHO POTENTIALLY VIOLATED?

- Potential violator name
- Potential violator business address
- Potential violator website
- Add Another Potential Violator - an option to add multiple potential tobacco product violators

U.S. Department of Health and Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español
Search FDA

Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System

Potential Tobacco Product Violations Reporting - Form FDA 3779

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Paperwork Reduction Act Statement
Form Approved: OMB NO. 0910-0716
Expiration Date: 07/31/2020

1 Potential Violation Information
2 Who Potentially Violated
3 Contact Information
4 Review and Submit

Who Potentially Violated

* Required field

Potential Violator 1

Who Potentially Violated? * Potential Violator Name

Potential Violator Address

Address Line 1 Address Line 2

City State

Postal/Zip Code

Website

If report is about a website, please provide website address here:

Include http:// or https:// before the address

[Add Another Potential Violator](#)

Previous Exit Next

Page Last Updated: 01/09/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Pycckий | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

ONLINE FORM FDA 3779 – PAGE 3 – CONTACT INFORMATION



SUBMITTER CONTACT INFORMATION

- Submitter name
- Submitter contact information (email, and telephone number) in case you wish to be contacted by the FDA for additional information.*

*Submitters can be anonymous.

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Search FDA

Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System

Potential Tobacco Product Violations Reporting - Form FDA 3779

SHARE TWEET LINKEDIN PINTEREST EMAIL PRINT

Paperwork Reduction Act Statement
Form Approved: OMB NO. 0910-0716
Expiration Date: 07/31/2020

1 Potential Violation Information 2 Who Potentially Violated 3 Contact Information 4 Review and Submit

Contact Information

* Required field

All reports will remain private to the extent allowed by law. For more information about FDA's internet policies, please visit:
<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm>

May we contact you if we need additional information?

No, I want to be anonymous. (However if you choose "No", FDA will not contact you and will not notify you via email that your complaint was received.)

Yes, FDA may contact me. (Please fill in contact information below.)

Previous Exit Next

Page Last Updated: 01/09/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Pycckий | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

ONLINE FORM FDA 3779 – PAGE 4 – REVIEW & SUBMIT



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Search FDA

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Home > Tobacco Products > Youth & Tobacco > Potential Tobacco Violation Reporting System

Potential Tobacco Product Violations Reporting - Form FDA 3779

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Paperwork Reduction Act Statement
Form Approved: OMB No. 0910-0716
Expiration Date: 07/31/2020

- 1 Potential Violation Information
- 2 Who Potentially Violated
- 3 Contact Information
- 4 Review and Submit

Review and Submit

Potential Violation Information [Edit Section](#)

Date Potential Violation Occurred 02/22/2022	State Potential Violation Occurred Alabama
Product Type Cigars	Tobacco Product Name
Potential Violation Type Sales to minors	Type of Potentially Violative Promotional Materials
Description of Potential Violation	Relevant Files Attached

Who Potentially Violated [Edit Section](#)

Who Potentially Violated Retailer	Potential Violator Name abc
Potential Violator Address 2022 Test Lane Alabama	Potential Violator Website

Contact Information [Edit Section](#)

All reports will remain private to the extent allowed by law. For more information about FDA's internet policies, please visit:
<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm>

Contact me for additional information
No, I want my report to be anonymous.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No.: 0910-0716
Expiration Date: 08/31/2023
(See page 3 for PRA Statement)

Potential Tobacco Product Violations Report

Directions:
Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

WHO can report? - Any member of the public.

Tell us:
WHEN did you see the potential violation?
WHERE did the potential violation occur?
WHAT is the potential violation?
WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date and State Where Violation Occurred

Date potential violation occurred (mm/dd/yyyy)	I do not recall the date this potential violation occurred <input type="checkbox"/>	State in which potential violation occurred
--	--	---

Description of Product

Type	Tobacco Brand
------	---------------

Potential violation type (choose all that apply)

<input type="checkbox"/> Sales to minors	<input type="checkbox"/> Free samples
<input type="checkbox"/> Flavored cigarette sales	<input type="checkbox"/> Self-service display/direct access to cigarette or smokeless tobacco
<input type="checkbox"/> Advertising/promotion/marketing	<input type="checkbox"/> Sale of cigarettes in packs of less than 20
<input type="checkbox"/> Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products	<input type="checkbox"/> Unsure

Type of potentially violative promotional materials (choose all that apply)

<input type="checkbox"/> Newspaper	<input type="checkbox"/> Price signage
<input type="checkbox"/> Magazine	<input type="checkbox"/> Posters
<input type="checkbox"/> Periodicals	<input type="checkbox"/> Coupons
<input type="checkbox"/> Billboard	<input type="checkbox"/> Internet
<input type="checkbox"/> Direct mail	<input type="checkbox"/> Unsure
<input type="checkbox"/> In-store advertisements	

Who potentially violated? (choose all that apply)

<input type="checkbox"/> Retailer	<input type="checkbox"/> Distributor
<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Unsure
<input type="checkbox"/> Importer	

FORM FDA 3779 (9/20) Page 1 of 3

ADDITIONAL WAYS TO REPORT A POTENTIAL TOBACCO PRODUCT VIOLATION

SUBMIT FORM FDA 3779



Accessing the Potential Tobacco Product Violation Report Form FDA 3779 online and email it to CTP Office of Compliance and Enforcement

- Fill out Form FDA 3779 online at <https://www.fda.gov/media/85811/download>
- Email completed Form FDA 3779 to CTP Compliance at CTPCompliance@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Potential Tobacco Product Violations Report		Form Approved: OMB No.: 0910-0716 Expiration Date: 08/31/2023 <i>(See page 3 for PRA Statement)</i>
Directions: Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products. WHO can report? - Any member of the public. Tell us: WHEN did you see the potential violation? WHERE did the potential violation occur? WHAT is the potential violation? WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce. To submit your report, complete the form below:		
Date and State Where Violation Occurred		
Date potential violation occurred (mm/dd/yyyy)	I do not recall the date this potential violation occurred <input type="checkbox"/>	State in which potential violation occurred <input type="text"/>
Description of Product		
Type <input type="text"/>	Tobacco Brand <input type="text"/>	
Potential violation type (choose all that apply)	<input type="checkbox"/> Sales to minors <input type="checkbox"/> Free samples <input type="checkbox"/> Flavored cigarette sales <input type="checkbox"/> Self-service display/direct access to cigarette or smokeless tobacco <input type="checkbox"/> Advertising/promotion/marketing <input type="checkbox"/> Sale of cigarettes in packs of less than 20 <input type="checkbox"/> Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products <input type="checkbox"/> Unsure	
Type of potentially violative promotional materials (choose all that apply)	<input type="checkbox"/> Newspaper <input type="checkbox"/> Price signage <input type="checkbox"/> Magazine <input type="checkbox"/> Posters <input type="checkbox"/> Periodicals <input type="checkbox"/> Coupons <input type="checkbox"/> Billboard <input type="checkbox"/> Internet <input type="checkbox"/> Direct mail <input type="checkbox"/> Unsure <input type="checkbox"/> In-store advertisements	
Who potentially violated? (choose all that apply)	<input type="checkbox"/> Retailer <input type="checkbox"/> Distributor <input type="checkbox"/> Manufacturer <input type="checkbox"/> Unsure <input type="checkbox"/> Importer	
FORM FDA 3779 (9/20)		Page 1 of 3

SUBMIT POTENTIAL TOBACCO PRODUCT VIOLATION THROUGH PHONE AND POST MAIL



The public can also report what they believe to be a violation of the Tobacco Control Act or other related regulations by calling or sending post mail to the Center for Tobacco Products.

- **Phone:** AskCTP at 1-877-287-1373 (Monday-Friday, 9:00 a.m. - 4:00 p.m. ET)
- **Mail:** Fill out the Form FDA 3779 online, print it, and send by mail to the following mailing address:

Potential Tobacco Products Violation Report

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993

WHAT HAPPENS TO MY POTENTIAL TOBACCO PRODUCT VIOLATION REPORT?



- FDA will evaluate all received reports
- If the product is regulated by a different federal or state agency or different part of FDA, we will forward the potential tobacco product violation to the applicable entity for review.
- The FDA may conduct additional investigations:
 - performing an inspection of a potential tobacco product violation manufacturer, distributor, or importer;
 - conducting a compliance check inspection of a potential tobacco product violation retailer; or
 - initiating, monitoring and surveillance of a potential tobacco product violation manufacturer or retailer website.
- FDA may determine that there is no evidence of a tobacco product violation, or we may find evidence of the reported potential tobacco product violation or of other potential tobacco product violations that require additional surveillance, monitoring, and/or inspections.

HOW TO REPORT TOBACCO PRODUCT HEALTH OR PRODUCT PROBLEMS IN USERS OR NONUSERS

SAFETY REPORTING PORTAL (SRP) – WHO CAN REPORT & WHAT TO REPORT



If you experience a health or safety problem or product quality problem with a tobacco product, report it to FDA's SRP at <https://www.safetyreporting.hhs.gov>

Who can report?

- Consumers or Concerned citizens **including Nonusers**
- Healthcare workers
- Companies that make, ship or sell tobacco products
- Researchers

What to report:

- Any new or worsened symptom or disease
- Toxic or allergic reactions
- Burn, seizure, breathing trouble, chest pain
- Damaged or defective products
- Labeling issues
- Abnormal product look, taste, or smell
- Product malfunction, failure, or interaction

SRP – LOG IN AS A GUEST OR ACCOUNT HOLDER



- Log in at <https://www.safetyreporting.hhs.gov>, as either a **Guest** or an **Account Holder**
- **Guest = Consumer, Concerned Citizen, or Healthcare Worker**
 - Option to remain anonymous
 - Cannot save draft reports to complete later
 - Can submit follow-up reports by retaining a "Report Key" from the submission confirmation message.

Begin Reporting Here

1. Login

EMAIL

PASSWORD

[Reset Password/Unlock Account or Reactivate Account](#)

Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

Or

You can do that here.

Account Benefits

- Save a draft
- Easier follow up submissions
- Faster data entry

Reporting Here

2. Report As Guest

Not ready to create an account but would like to submit a report?

Or

You can do that here.

Account Benefits

- Save a draft
- Easier follow up submissions
- Faster data entry

Submit a Safety Report?

...in certain professional roles, such as the ...ed by law to submit safety reports under ...ers, Processors, Packers, and Holders ...n approved drug product or a manufacturer, ...ker listed on the label of any marketed drug ...ers ...pr-investigators of investigational drugs and ...ent manufacturers, packers, and distributors ...are providers, public health officials, and ...other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting.](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES - USA
USA.gov
FDA U.S. Food and Drug Administration
NATIONAL INSTITUTES OF HEALTH

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

SRP – NEW GUEST REPORT FOR CONSUMERS AND CONCERNED CITIZENS

After logging into SRP as a Guest, Consumers and Concerned Citizens must answer a few questions to gain access to the Tobacco Product Report.

***Who are You?**

- A private citizen, business or veterinary provider submitting a voluntary report
- A federal, state or local government public health official submitting a reportable food report about human and/or animal food
- A healthcare professional or researcher reporting a tobacco product problem
- A manufacturer reporting a tobacco product problem
- A manufacturer, investigator, sponsor or applicant of a drug or biologic product
- A manufacturer, packer or distributor of a human dietary supplement
- A food facility or responsible party that manufactures, processes, packs or holds food submitting a reportable food report

***What do you think caused the issue?**

Tobacco Products

SRP – NEW GUEST REPORT FOR HEALTHCARE WORKERS

After logging into SRP as a Guest, Healthcare Workers must answer a few questions to gain access to the Tobacco Product Report.

***Who are You?**

- A private citizen, business or veterinary provider submitting a voluntary report
- A federal, state or local government public health official submitting a reportable food report about human and/or animal food
- A healthcare professional or researcher reporting a tobacco product problem
- A manufacturer reporting a tobacco product problem
- A manufacturer, investigator, sponsor or applicant of a drug or biologic product
- A manufacturer, packer or distributor of a human dietary supplement
- A food facility or responsible party that manufactures, processes, packs or holds food submitting a reportable food report

***Select the report to begin**

- Tobacco Researcher/Investigator Report: Researchers, principal investigators, clinical study sponsors or other designated research team members reporting a problem with a marketed or investigational tobacco product associated with tobacco research
- Tobacco Product Report (Health care professionals): Health care professionals/workers, including those in public health and first response, reporting a problem with a tobacco product

SRP – LOG IN & SUBMIT REPORT AS ACCOUNT HOLDER



- Create an account then use it to log in at <https://www.safetyreporting.hhs.gov>
- When Reporting as an Account Holder:
 - Researchers and Manufacturers must create an account to submit a report
 - Must provide contact information
 - Can save a draft of any report to complete later
 - Can easily submit follow-up reports from a personal "My Reports" page (for corrections or additional information)
 - Can set up a group account to review and submit reports of other group members

Begin Reporting Here

1. Login

EMAIL

PASSWORD

[Reset Password/Unlock Account or Reactivate Account](#)

Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

Reporting Here

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

Submit a Safety Report?

...in certain professional roles, such as the ...red by law to submit safety reports under ...ers, Processors, Packers, and Holders ...an approved drug product or a manufacturer, ...cker listed on the label of any marketed drug ...ers ...or-investigators of investigational drugs and ...ent manufacturers, packers, and distributors ...care providers, public health officials, and ...other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting.](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
USA.gov
FDA U.S. Food and Drug Administration
NATIONAL INSTITUTES OF HEALTH

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

SRP: CONFIRM YOU ARE IN THE TOBACCO PRODUCT REPORT



Welcome Guest HOME FAQS RELATED LINKS CONTACT US FEEDBACK HELP EN ESPAÑOL

Name: **Tobacco Product Report**
(Manufacturer, Concerned Citizen or Healthcare Professional) and Created By: unknown

ID: FPSR68084 (1)

Created: 05/26/2022

- Introduction**
- Report Information
- Contact Information
- Problem Summary
- Main Tobacco Products**
- Other Tobacco Products**
- Additional Information
- Attachments

Introduction

*** = Required Field**

Tobacco Product Reports (TPR)

The FDA regulates all tobacco products in the U.S. Tobacco products are made or derived from tobacco and include any parts that are needed for their use. For example, both a pipe device and the pipe tobacco are regulated by the FDA.

Who can report by using this TPR SRP path?

- People who use tobacco products
- People affected by someone else's tobacco use
- Concerned members of the public
- Healthcare workers
- Companies involved in making, shipping, and selling tobacco products

How do I use this TPR SRP path to submit a report?

When possible, please submit a separate report for each affected person. After you complete the "Report Information" 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, create an account and save the draft report to finish later.

What happens when I submit a report?

FDA staff will review your report. In general, submitters will not get a response from FDA. FDA may contact you if more details are needed and you give us at least one way to reach you. **You will not get health advice or health care from FDA** - please call or see your local doctor or clinic if needed.

SRP: SEE MORE INSTRUCTIONS IN FAQs



<https://www.safetyreporting.hhs.gov/SRP2/en/FAQ.aspx>

Safety Reporting Portal

ABOUT THE PORTAL SAFETY REPORT DIRECTORY **FAQS** RELATED LINKS CONTACT US EN ESPAÑOL

The Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

Parts of this website have been translated from English to Spanish. Pages that have been translated have an "En Espanol" link in the upper right part of the page. Click this link to see the page in Spanish (Espanol). Click "In English" to see the page in English. In the case of any discrepancy in meaning, the English version is considered official. Currently, report questions are only in English and reports should only be submitted in English. Thank you for using the FDA Safety Reporting Portal.

Begin Reporting Here

1. Login

EMAIL

PASSWORD

[Reset Password/Unlock Account or Reactivate Account](#)

Remember me

2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

The SRP tobacco questionnaires are not available in a paper or fillable PDF format.

HOW TO REPORT THE RIGHT TOBACCO PRODUCT INFORMATION TO THE RIGHT PLACE

Tobacco-Related Issues	Where to Report
Potential tobacco-related violation of the Food, Drug and Cosmetic Act and associated regulations	https://www.accessdata.fda.gov/scripts/ptvr/index.cfm
Health problem (adverse experience) or a product quality problem with a tobacco product	https://www.safetyreporting.hhs.gov
Tobacco or nicotine poisoning needing urgent medical care	<p>If a person has collapsed, had a seizure, has trouble breathing, or can't be awakened, call 911 right away.</p> <p>For live medical advice, call the Poison Control Center: 1-800-222-1222.</p> <p>You may later submit an SRP report that includes the final outcome of the problem.</p>
Human health problem or product problem with a product that claims to help with quitting tobacco	https://www.accessdata.fda.gov/scripts/medwatch/index.cfm
Animal Health problem-effect of tobacco product on an animal	https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm
Comment on a proposed regulation	http://www.regulations.gov
Complaint about CTP, an existing tobacco law (final regulation), or the government	CTPOmbudsman@fda.hhs.gov
Information to share about tobacco products that is not related to a health or product problem	Contact the product's manufacturer or email AskCTP@fda.hhs.gov or 1-877-CTP-1373
Other question or concern related to tobacco products	AskCTP@fda.hhs.gov or 1-877-CTP-1373

END

FDA

Thank you!