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
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
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
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
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
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
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
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.
ADDITIONAL WAYS TO REPORT A POTENTIAL TOBACCO PRODUCT VIOLATION
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
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
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](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.
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
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
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
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.
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
<table>
<thead>
<tr>
<th>Tobacco-Related Issues</th>
<th>Where to Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health problem (adverse experience) or a product quality problem with a tobacco product</td>
<td><a href="https://www.safetyreporting.hhs.gov">https://www.safetyreporting.hhs.gov</a></td>
</tr>
<tr>
<td>Tobacco or nicotine poisoning needing urgent medical care</td>
<td>If a person has collapsed, had a seizure, has trouble breathing, or can’t be awakened, call 911 right away. For live medical advice, call the Poison Control Center: 1-800-222-1222. You may later submit an SRP report that includes the final outcome of the problem.</td>
</tr>
<tr>
<td>Human health problem or product problem with a product that claims to help with quitting tobacco</td>
<td><a href="https://www.accessdata.fda.gov/scripts/medwatch/index.cfm">https://www.accessdata.fda.gov/scripts/medwatch/index.cfm</a></td>
</tr>
<tr>
<td>Animal Health problem-effect of tobacco product on an animal</td>
<td><a href="https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm">https://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm</a></td>
</tr>
<tr>
<td>Comment on a proposed regulation</td>
<td><a href="http://www.regulations.gov">http://www.regulations.gov</a></td>
</tr>
<tr>
<td>Complaint about CTP, an existing tobacco law (final regulation), or the government</td>
<td><a href="mailto:CTPOmbudsman@fda.hhs.gov">CTPOmbudsman@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Information to share about tobacco products that is not related to a health or product problem</td>
<td>Contact the product’s manufacturer or email <a href="mailto:AskCTP@fda.hhs.gov">AskCTP@fda.hhs.gov</a> or 1-877-CTP-1373</td>
</tr>
<tr>
<td>Other question or concern related to tobacco products</td>
<td><a href="mailto:AskCTP@fda.hhs.gov">AskCTP@fda.hhs.gov</a> or 1-877-CTP-1373</td>
</tr>
</tbody>
</table>
Thank you!