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

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:

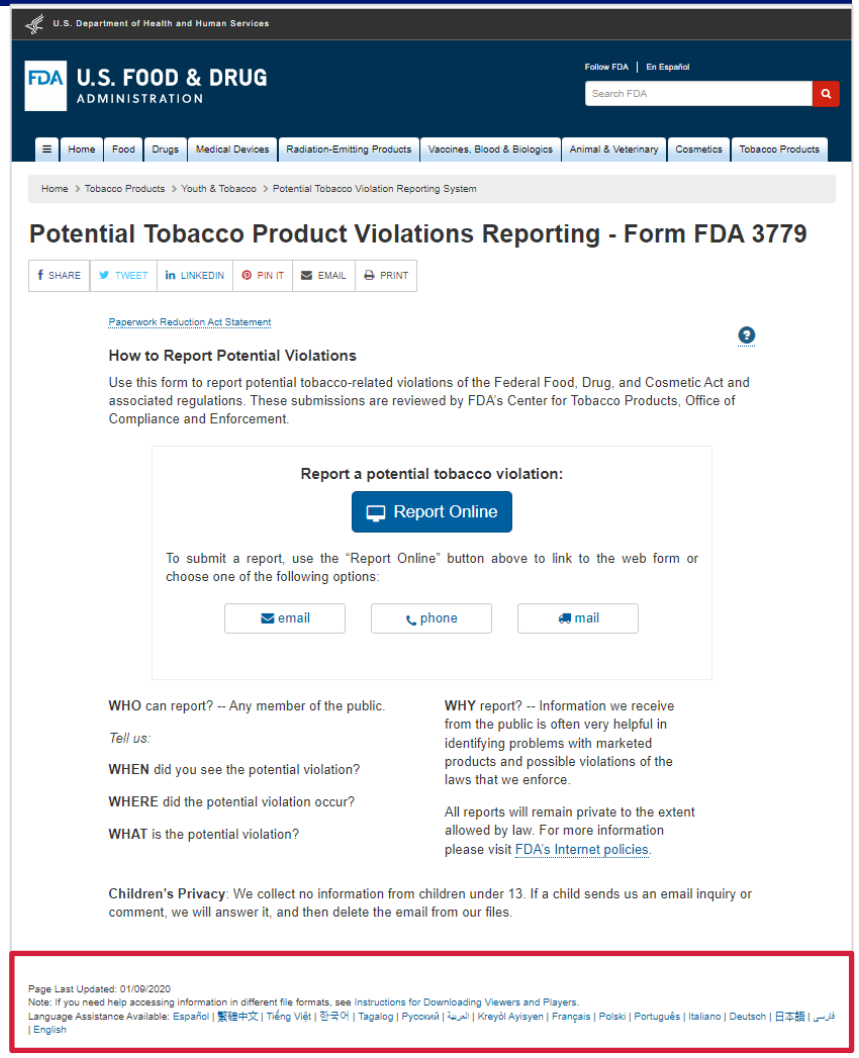
- Sale of single cigarettes
- Sales of tobacco to an underage purchaser (under age 21)
- Sale of flavored tobacco products
- Sale of tobacco products through vending machines and self-service displays, except in adult-only facilities
- Illegal marketing and advertising of tobacco products
  - Describing 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

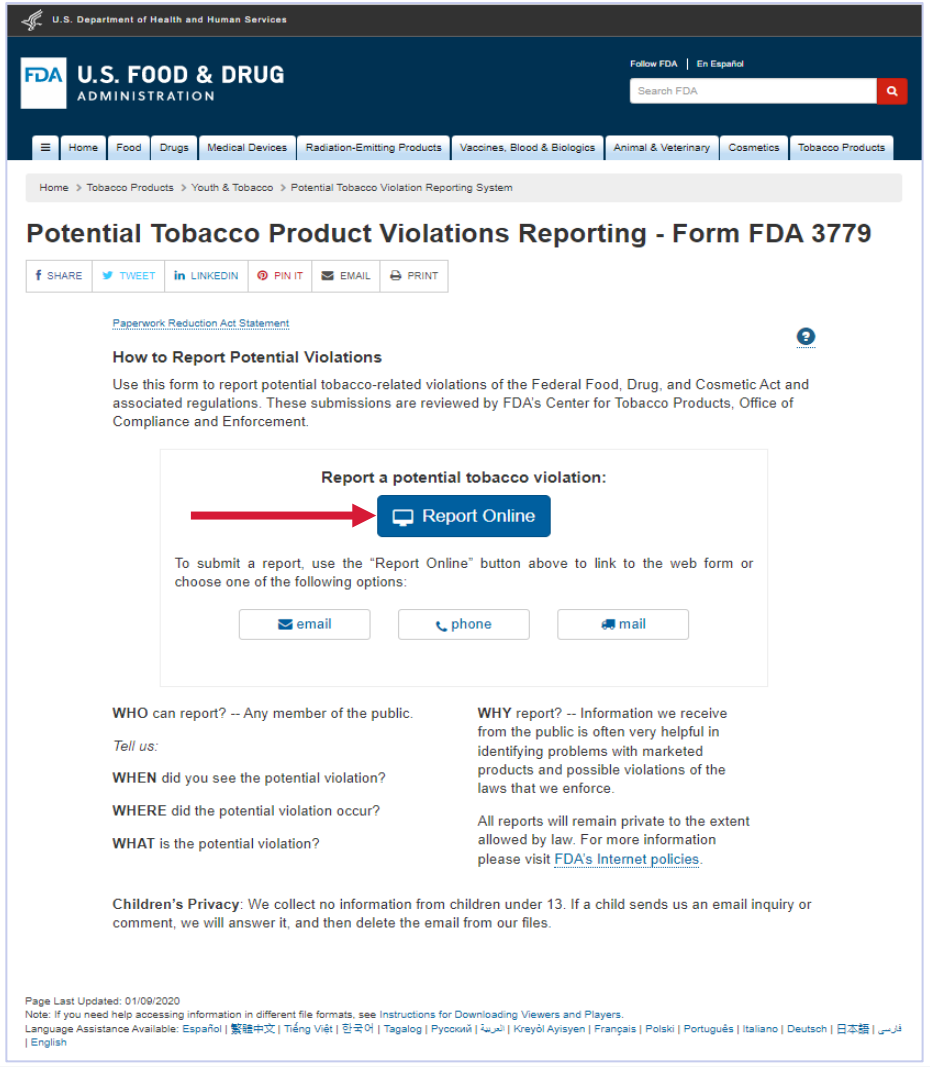


ONLINE FORM FDA 3779 – INITIAL PAGE

POTENTIAL TOBACCO PRODUCT VIOLATION REPORTING FORM FDA 3779

Home page:
https://www.accessdata.fda.gov/scripts/ptvr/index.cfm

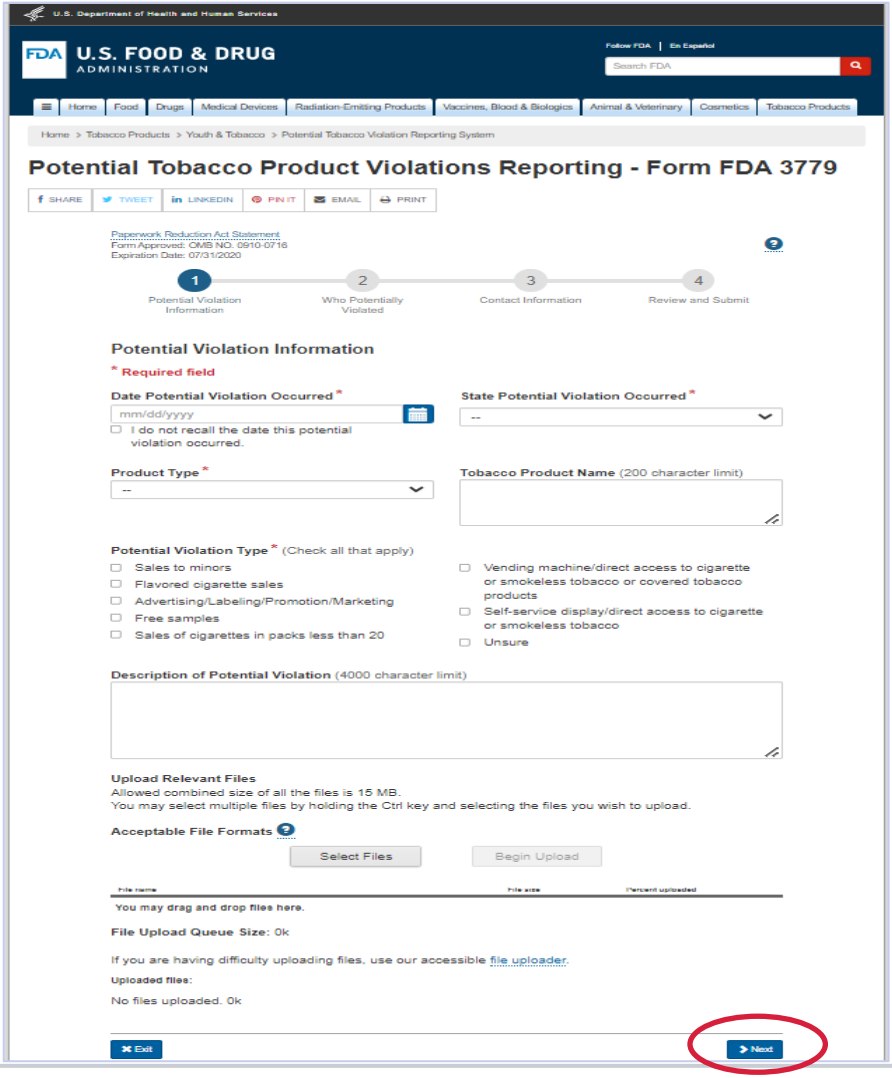
Click **Report Online** box to continue



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

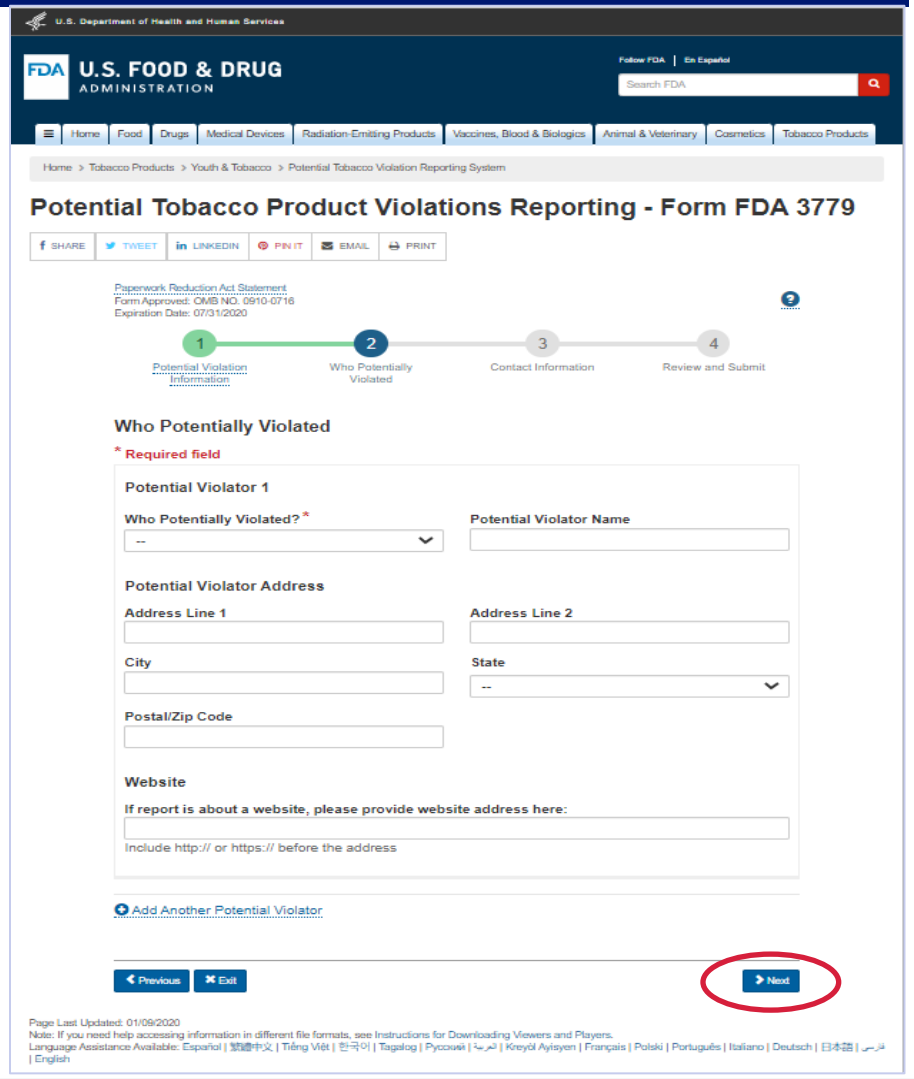


ONLINE FORM FDA 3779 – PAGE 2 – POTENTIAL VIOLATOR

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

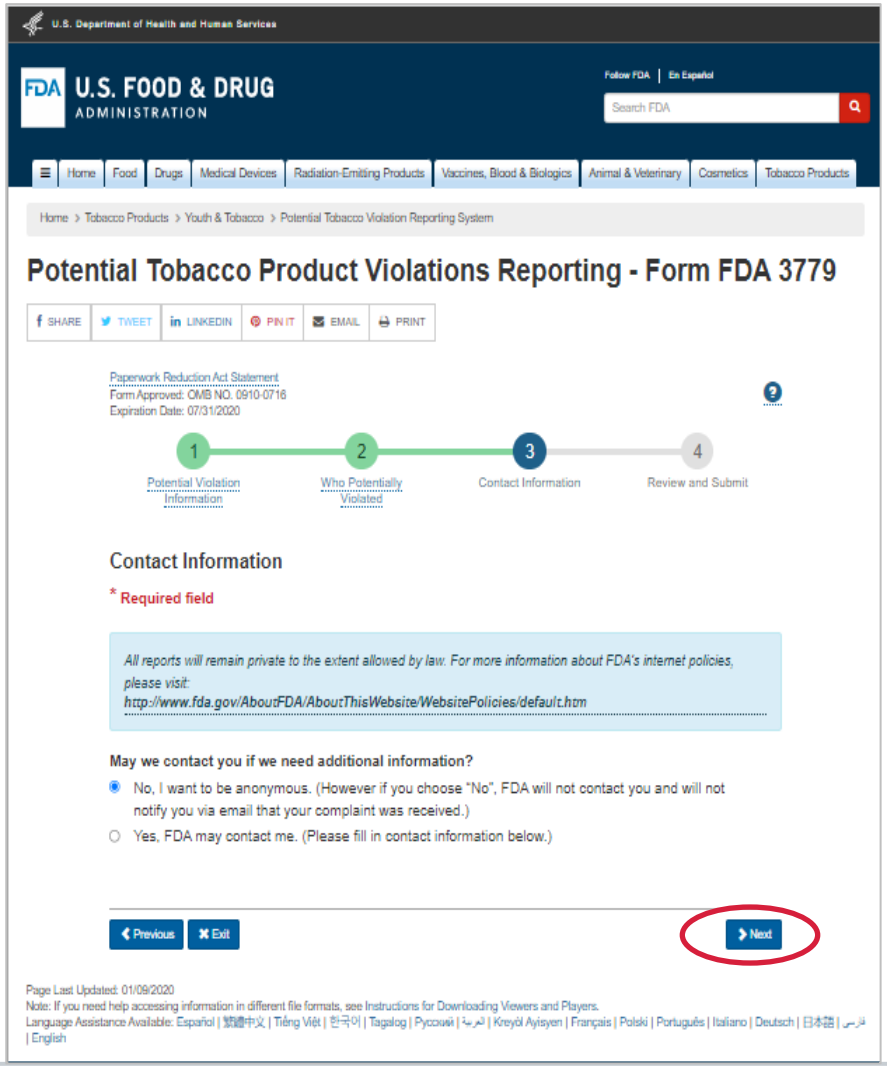


ONLINE FORM FDA 3779 – PAGE 3 – CONTACT INFORMATION

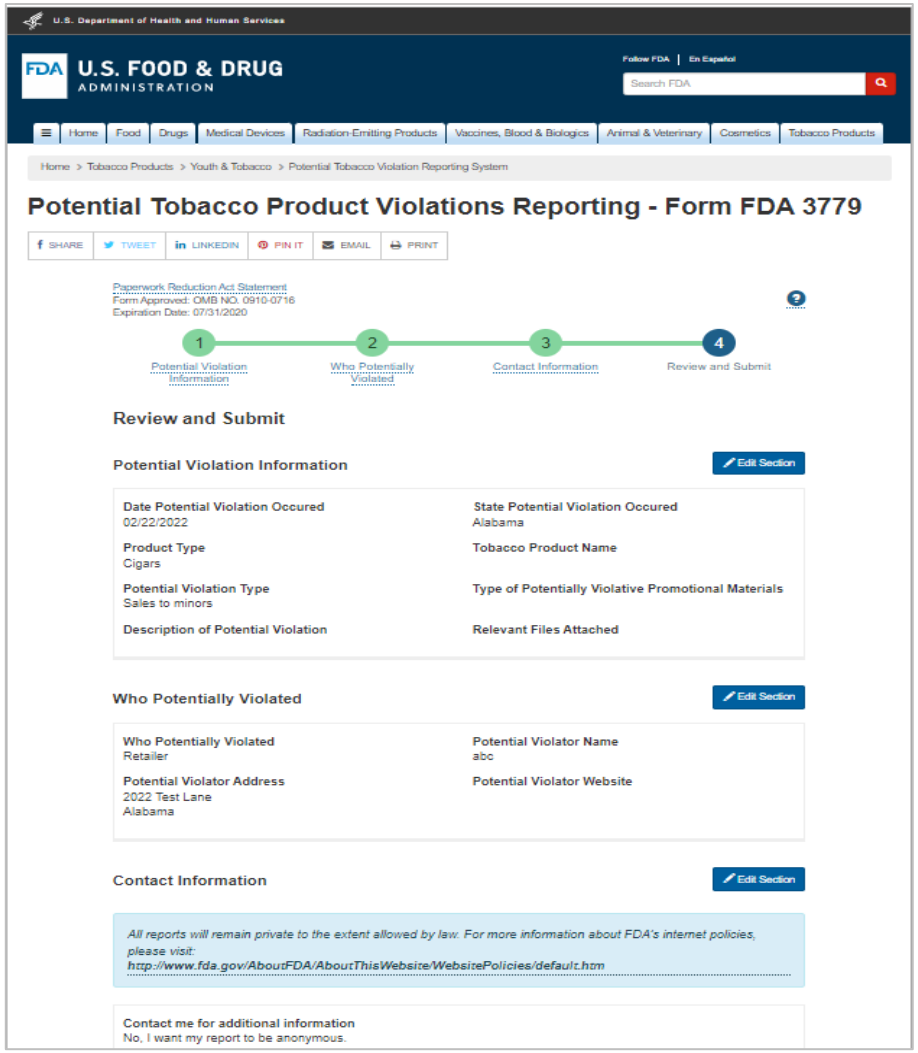
SUBMITTER CONTACT INFORMATION

- 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.



ONLINE FORM FDA 3779 – PAGE 4 – REVIEW & SUBMIT



U.S. Department of Health and Human Services

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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 Occured 02/22/2022	State Potential Violation Occured 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

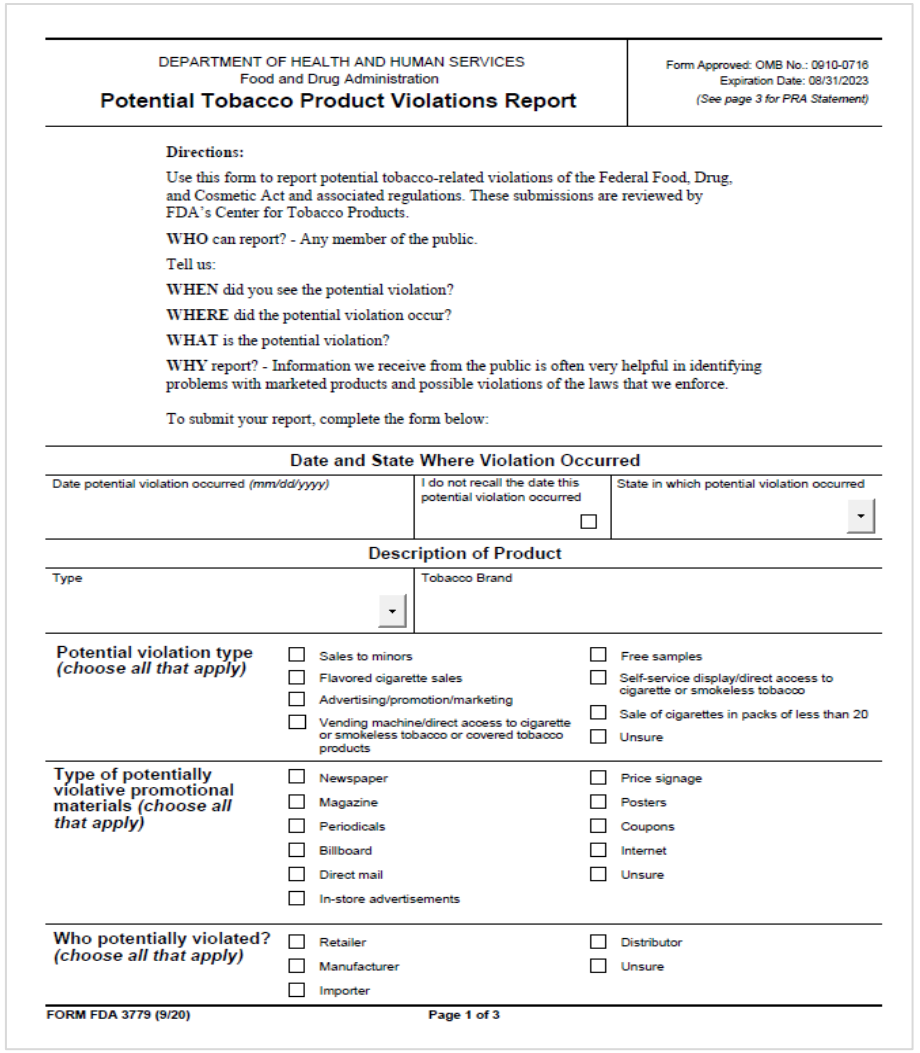
Who Potentially Violated — Edit Section

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

Potential Tobacco Product Violations Report

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

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 ☐	State in which potential violation occurred

Description of Product

Type	Tobacco Brand

Potential violation type *(choose all that apply)*

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

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

☐ Newspaper
☐ Magazine
☐ Periodicals
☐ Billboard
☐ Direct mail
☐ In-store advertisements
☐ Price signage
☐ Posters
☐ Coupons
☐ Internet
☐ Unsure

Who potentially violated? *(choose all that apply)*

☐ Retailer
☐ Manufacturer
☐ Importer
☐ Distributor
☐ Unsure

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

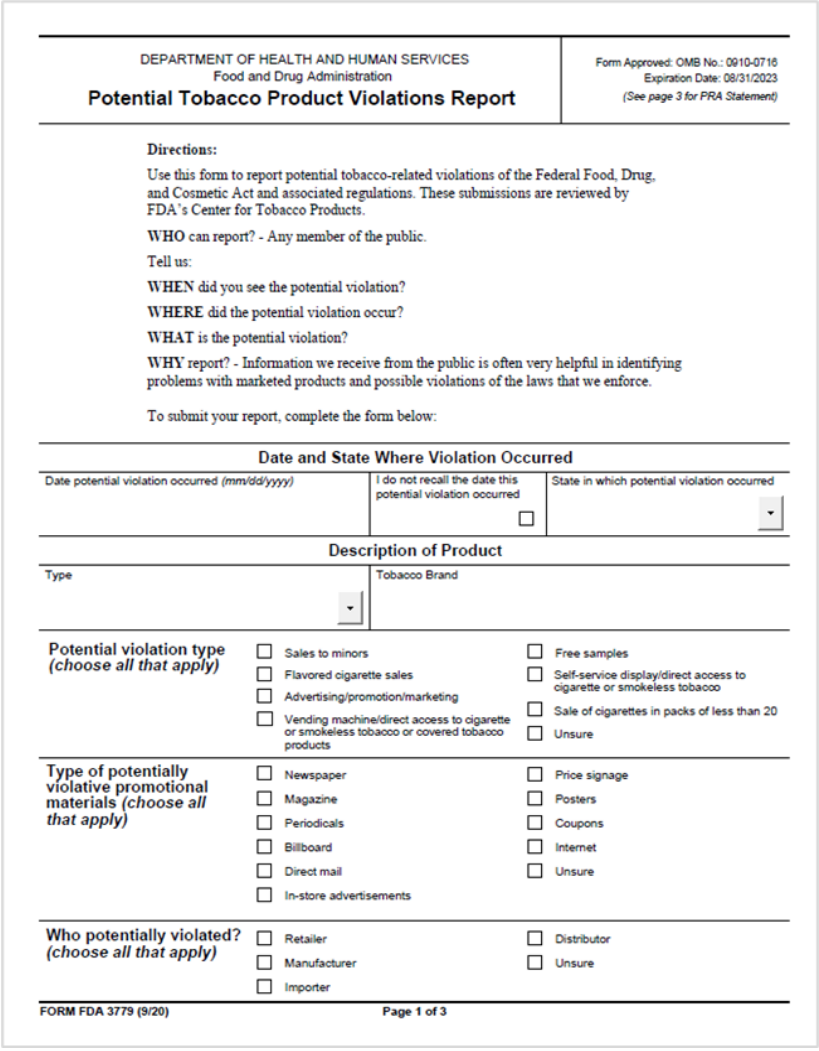
ADDITIONAL WAYS TO REPORT A POTENTIAL TOBACCO PRODUCT VIOLATION

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



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Type	Tobacco Brand

Potential violation type *(choose all that apply)*

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- ☐ Flavored cigarette sales
- ☐ Advertising/promotion/marketing
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- ☐ Self-service display/direct access to cigarette or smokeless tobacco
- ☐ Sale of cigarettes in packs of less than 20
- ☐ Unsure

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

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- ☐ Magazine
- ☐ Periodicals
- ☐ Billboard
- ☐ Direct mail
- ☐ In-store advertisements
- ☐ Price signage
- ☐ Posters
- ☐ Coupons
- ☐ Internet
- ☐ Unsure

Who potentially violated? *(choose all that apply)*

- ☐ Retailer
- ☐ Manufacturer
- ☐ Importer
- ☐ Distributor
- ☐ Unsure

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**

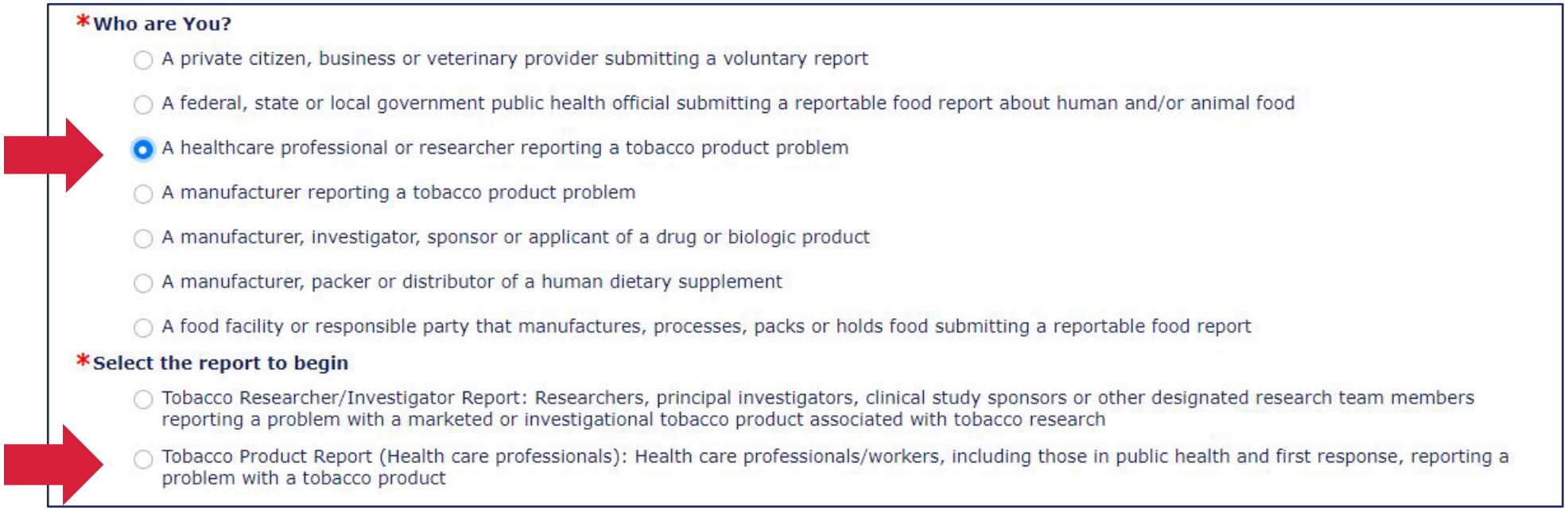
- **Guest = Consumer, Concerned Citizen, or Healthcare Worker**
  - Option to remain anonymous
  - Cannot save draft reports to complete later
  - Can submit follow-up reports by retaining a "Report Key" from the submission confirmation message.

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.

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.

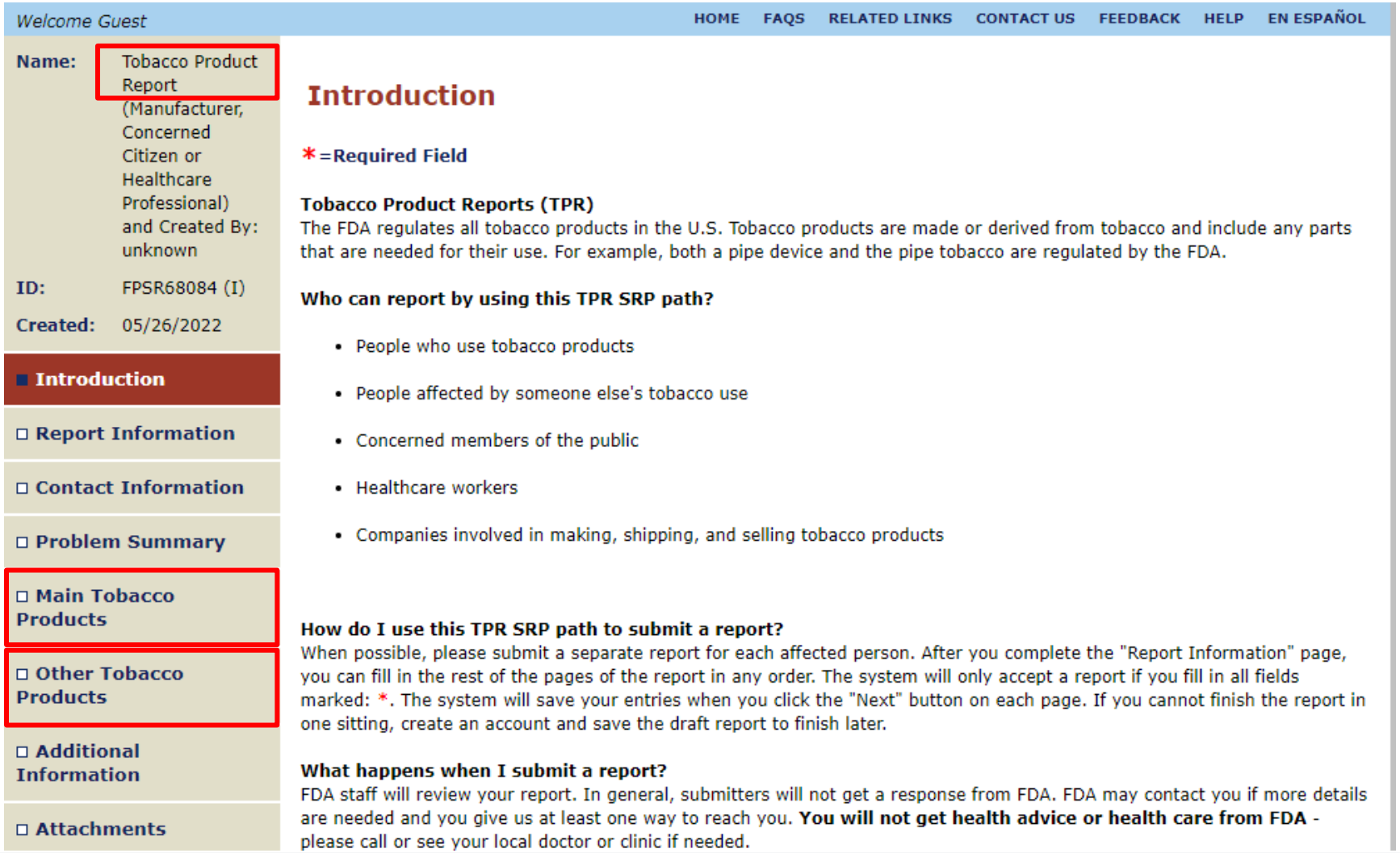


SRP – LOG IN & SUBMIT REPORT AS ACCOUNT HOLDER

- **Create an account then use it to log in at https://www.safetyreporting.hhs.gov**

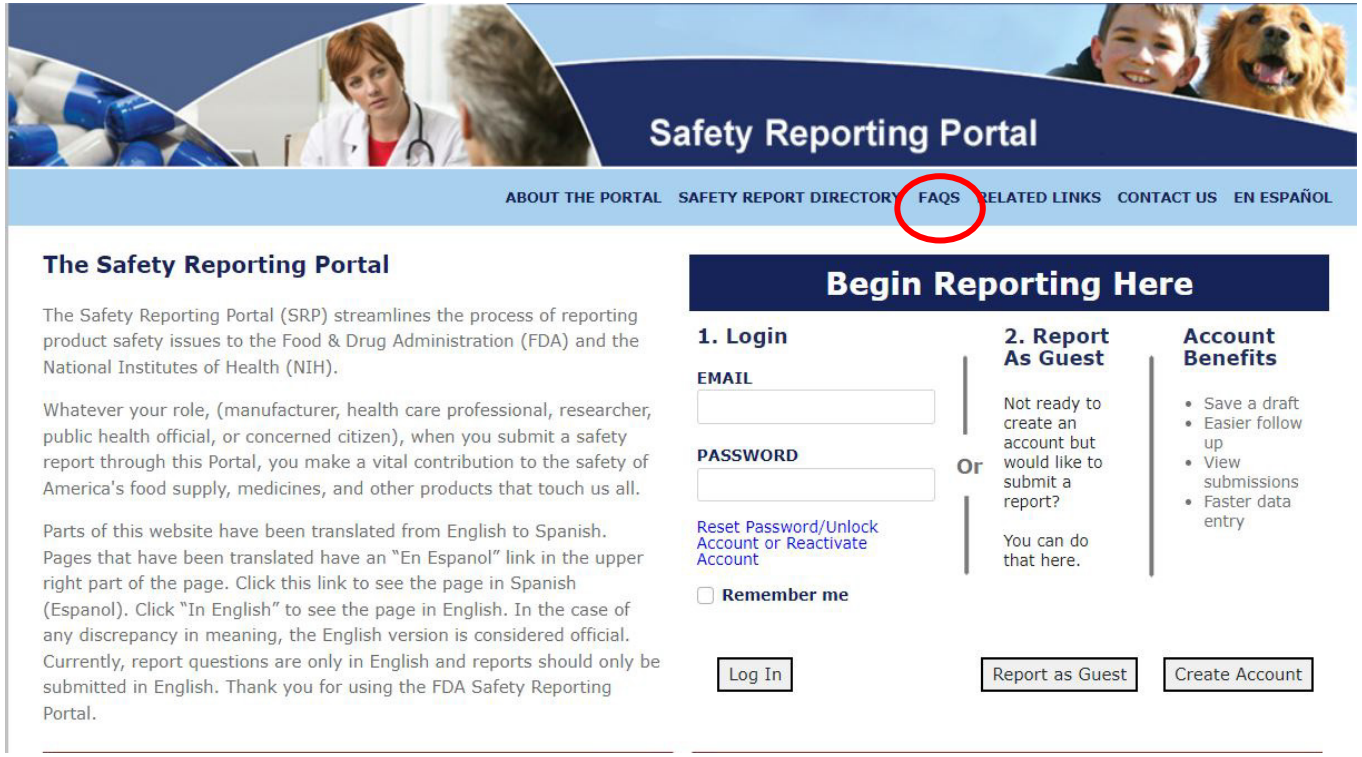
- **When Reporting as an Account Holder:**
  - Researchers and Manufacturers must create an account to submit a report
  - Must provide contact information
  - Can save a draft of any report to complete later
  - Can easily submit follow-up reports from a personal "My Reports" page (for corrections or additional information)
  - Can set up a group account to review and submit reports of other group members

SRP: CONFIRM YOU ARE IN THE TOBACCO PRODUCT REPORT



SRP: SEE MORE INSTRUCTIONS IN FAQS

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



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	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.
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

Thank you!