

POTENTIAL TOBACCO VIOLATION REPORT (PTVR)

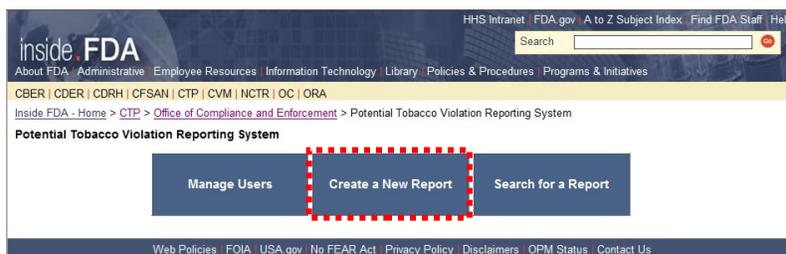
CALL CENTER GENERAL INSTRUCTIONS

Step 0 – Refer the caller to the PTVR System

- Determine if the caller is reporting a potential violation of the FD&C Act.
 - If so, offer the caller the option of submitting his or her report online, using the *external* web form:
 - [Tobacco Products homepage](#) > [Youth & Tobacco](#) > [Report Potential Tobacco Product Violations](#)
 - If the caller is not open to the online option, you will need to create a report using the *internal* web form: <https://sslintranetappsfb.fda.gov/scripts/ptvradmin/index.cfm>
- If the caller is not calling to report a violation, follow your normal procedures in HPSM.

Step 1 – Open the internal PTVR System and select “Create a New Report”

<https://sslintranetappsfb.fda.gov/scripts/ptvradmin/index.cfm>



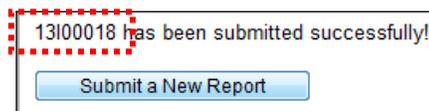
Step 2 – Gather and Enter PTVR Information

Our goal is to capture all relevant information reasonably available to the caller at the time he or she first calls.

- While you have the caller on the phone, you may choose to enter information directly into the internal web form. Detailed instructions below will help you organize your call.
- Alternatively, you may take notes during your call on a paper PDF of Form FDA 3779 and transfer the information from the PDF to the internal web form. A copy of the PDF is available here (would suggest printing and having several blanks ones available and ready to fill out):
<http://www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/UCM330951.pdf>

Step 3 – Finally, Submit the Report

- Finally, Select the **Submit** button at the bottom of the screen, and you will be sent to a confirmation page which will display the Report ID.



DETAILS FOR STEP 3: Gather and Enter PTVR Information

<https://ssl.intranet.appslb.fda.gov/scripts/ptvradmin/index.cfm?action=report.new>

POTENTIAL VIOLATOR INFORMATION

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Who Potentially Violated:

Type: *	--	Address Line 1:	
Name:		Address Line 2:	
Violation		City:	
Website:		State:	Puerto Rico
		Zip:	

+ Add Another

- **Type:**
 - Ask what type of business the caller is reporting information about, you may read them the options in the drop down. *If the caller is unsure, or this information is not provided (for example in a voicemail) select unsure.*

POTENTIAL VIOLATOR INFORMATION

Who Potentially Violated:

Type: *	--
Name:	Distributor
Violation	Importer
Website:	Manufacturer
	Packager
	Retailer
	Wholesaler
	Unsure

- Obtain the business's name, website, and address if available.

Notes:

Some callers may want to report more than one business or location. Select **+Add Another** to add an additional business.

POTENTIAL VIOLATION INFORMATION

POTENTIAL VIOLATION INFORMATION

Date Occurred: * Date Received: * State Occurred: * --

I do not recall the date this potential violation occurred.

Potential Violation Type: * Check all that apply.

Sales to minors Flavored cigarette sales Advertising/promotion/marketing

Free samples Sale of cigarettes in packs of less than 20 Unsure

Vending machine/self-service display/direct access to cigarette or smokeless tobacco

Description of Potential Violation:

1000 character limit.

Relevant Files: Allowed combined size of all the files is 8 MB. [? Acceptable File Formats](#)

Uploaded files:

No files uploaded.

- **Date Occurred:, Date Received:, State Occurred:**
 - Ask for the date the violation occurred and in what state?
 - If the caller does not recall the date, select the **I do not recall...** check box.
 - If the caller is unsure of the state in which the violation occurred, select N/A.
 - Date Received is the date that CTP received the call.
- **Potential Violation Type:, Description of Potential Violation:**
 - Ask the caller to identify the potential violation, you may read to the caller the options in the **Potential Violation Type:** field.
 - If the caller is reporting something other than those listed, then check Unsure.
 - **Important:** Include all the information the caller provides about the potential violator or potential violation into **Description of Potential Violation:**.
- **Relevant Files:**
 - If the caller wishes to send an attachment, tell the caller to email the file to ctpcompliance@fda.hhs.gov, and to include the PTVR ID number in the email.
 - You will generate a PTVR ID number after you submit the report.

Notes:

If the caller wishes to mail physical samples, photographs, or other evidence ask the caller to describe what he or she would like to send and record this information in the **Description of Potential Violation:**. Let the caller know that you will have the proper office contact him or her regarding whether CTP can accept the materials and if so where to send them.

POTENTIAL VIOLATION INFORMATION continued

Potential Violation Type: * Check all that apply.

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

- **Potential Violation Type: Advertising/promotion/marketing** (selected)
 - If **Advertising/promotion/marketing** is selected, additional options for **Type of Potentially Violative Promotional Materials:** will appear below
 - You may read to the caller the options in the **Type of Potentially Violative Promotional Materials:** field.

Type of Potentially Violative Promotional Materials: * Check all that apply.

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

Notes:

☐ **Product Information**

PRODUCT INFORMATION

Product Type: * -- Tobacco Brand: [Text Input Field]

200 character limit.

- **Product Type:**
 - The caller may have already provided the product type in their description, but please confirm the type here. **Important:** We are authorized to provide only the following options: 1) Cigarette 2) Smokeless, and 3) Roll-your-own. If the caller identifies something other than these three options, select Other Tobacco Product, but please describe the product in the description of the potential violation field.

- **Tobacco Brand:**
 - Ask the caller to indicate the tobacco brand, if available.

Notes:

□ **SUBMITTER INFORMATION**

SUBMITTER INFORMATION

Correspondence Method: * CTP Call Center Complaint Source: General Public Contact: * Yes No

• **Correspondence Method:**

- Select **CTP Call Center** for calls to the call center (do not select any of the other options).
- Select **DCC** for PDF forms entered into

SUBMITTER INFORMATION

Correspondence Method: * [CTP Call Center] (dropdown menu open)

-
- ASKCTP Mailbox
- Adverse Event from OS
- CTP Call Center**
- CTP Compliance Mailbox
- DCC
- Exec Sec Mailbox
- Flavored Cigarette Reporting Form
- ORA District
- Tobacco Industry Questions Mailbox
- Other

Internal Comments: [Text area]

1000 character limit.

• **Complaint Source:**

- Ask the caller if he or she would like to identify themselves as being a representative or member of particular company, agency, or organization, or as a consumer or member of the general public. Select the most appropriate (options are in the drop down box).

SUBMITTER INFORMATION

Correspondence Method: * CTP Call Center Complaint Source: [General Public] (dropdown menu open)

-
- Advocacy Group
- Consumer
- FDA Internal
- General Public
- Health Care Provider
- Local Government Agency
- Other Federal Agency
- Retailer
- State Government Agency
- Tobacco Industry
- Unknown

Send Submitter an Acknowledgement

Name: [Text box] Email: [Text box]

Affiliation: [Text box] Phone: [Text box]

Address Line 1: [Text box] City: [Text box]

Address Line 2: [Text box] State: [Text box]

Notes:

Limit choosing **Consumer** to situations where a person indicates that they actually use tobacco products, otherwise select **General Public**.

□ **SUBMITTER INFORMATION** *continued*

SUBMITTER INFORMATION		
Correspondence Method: *	CTP Call Center	Complaint Source: General Public
Contact: *	<input type="radio"/> Yes <input checked="" type="radio"/> No	

- **Contact:**

- If the answer to either of the following questions is no, please document the response in **Internal Comments:**

- Ask the caller if we may contact them if we need additional information.

- If yes, select yes and the additional fields below will appear.
- Include a name and, either or both, a phone number or email address (required).
- If no, do not proceed to the next question.

- Ask the caller if he or she would like confirmation of the submission.

- If yes, select yes and the additional fields below will appear.
- Check the box **Send Submitter an Acknowledgment**
- Include a name and, either or both, a phone number or email address (required).

SUBMITTER INFORMATION		
Correspondence Method: *	CTP Call Center	Complaint Source: General Public
Contact: *	<input checked="" type="radio"/> Yes <input type="radio"/> No	
<input type="checkbox"/> Send Submitter an Acknowledgement		
Name:	<input type="text"/>	Email: <input type="text"/>
Affiliation:	<input type="text"/>	Phone: <input type="text"/> - <input type="text"/> - <input type="text"/> Ext. <input type="text"/>
Address Line 1:	<input type="text"/>	City: <input type="text"/>
Address Line 2:	<input type="text"/>	State: -- <input type="text"/> Zip: <input type="text"/>
Internal Comments: <input type="text"/>		
1000 character limit.		

Notes:

Include in **Internal Comments:** any additional information that you may want to send on to OCE.