

CENTER FOR TOBACCO PRODUCTS OFFICE OF SMALL BUSINESS ASSISTANCE

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

The Center for Tobacco Products' Office of Small Business Assistance (OSBA) provides technical and other non-financial assistance to small tobacco manufacturers and other small tobacco product businesses to help them comply with the provisions of the Federal Food, Drug, and Cosmetic Act related to tobacco product regulation.

TYPES OF ASSISTANCE

- Compliance Webinars
- Manufacturer Assistance
- Retailer Education Materials
- Responses to Questions and Inquiries
- Commonly Asked Questions

Best of all - everything is free!

COMPLIANCE WEBINARS



FDA's Center for Tobacco Products (CTP) hosts a series of webinars on federal tobacco regulations to provide compliance education and information to retailers and small business manufacturers.

[Compliance Webinars](#)

ASSISTANCE FOR MANUFACTURERS

- Market and Distribute a Tobacco Product
- How to pay User fees
- Tobacco Registration and Listing Module – Next Generation (TRLM NG)

Tobacco Registration & Product Listing Module
NEXT GENERATION
U.S. Department of Health and Human Services

In preparation for the upcoming Bi-annual and Annual updates to tobacco registration and product listing:

- Section 905(b) of the FD&C Act requires establishment registrations to be re-submitted annually on or before December 31st of each year
- Section 905(i)(2) of the FD&C Act requires that certain changes in the product list be submitted bi-annually, once during June and once during December
- For more information on the changes to product listing to be submitted bi-annually see the [Section 905 Food, Drug & Cosmetic Act Annual Registration Guidance](#)

To begin, log into your TRLM NG account to view and update your registration and product listing including material files prior to the deadline: December 31st, 2020 at 11:59pm EST.

Register Your Tobacco Establishments & Products

Create an account to register your tobacco manufacturing establishment(s) and manage your product listing as per the FDA's Section 905 of the Food, Drug, and Cosmetic Act (FD&C Act).

[Create Account](#)

FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

Welcome to the CTP Portal

Login

*Username:

[Forgot Username?](#)

*Password:

[Forgot Password?](#)

I Agree

Terms of Use
You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording; anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials. 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.

What is the CTP Portal?
The U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) developed the CTP Portal as part of its initiative to improve submission processing and to foster interaction with industry. The CTP Portal allows industry to use the embedded upload feature to transmit eSubmitter-generated submissions; this new transmission method offers industry an alternative to the Agency's existing WebTrader Hosted Solution. The [eSubmission File Formats and Specifications](#) document is available to provide an overview of the technical file formats and data specifications related to submitting electronic files to CTP.

The CTP Portal is intended for use by regulated tobacco industry, including manufacturers, importers, and distributors who make submissions to CTP. The CTP Portal should improve transparency and facilitate communication to speed issue resolution that may otherwise hinder processing and/or access to industry submissions.

RETAILER EDUCATION MATERIALS

To give retailers all the tools they need to comply with tobacco regulations, the FDA's Center for Tobacco Products has developed an education program called "This is Our Watch."



[Learn more about FDA "This Is Our Watch"](#)

FDA's free digital age verification calendar helps retailers quickly determine if a customer is old enough to legally purchase tobacco products. Under federal law, the minimum age to purchase tobacco products is 21.

Digital Age Verification Calendar



To support the public health goals of the Tobacco Control Act, FDA provides guidance to help industry understand and comply with all regulations and the law.

To search for a guidance related to tobacco:

- Go to [Search for FDA Guidance Documents](#)
- Scroll down to Guidance Document Search
- Filter by FDA Organization, Center for Tobacco Products
- Use other filters, as needed
- You can also access a list of [withdrawn/replaced guidances](#)

The Office of Small Business Assistance provides responses to customer and stakeholder inquiries and questions related to FDA's tobacco laws.

OSBA's responses include web pages with links to detailed information on regulations, rules, and requirements for manufacturers of tobacco products.

COLLABORATION

To report what you believe to be a violation of the Tobacco Control Act or other related regulations, you can:

- [Submit an Online Form](#)
- Contact the Tobacco Call Center using CTP's toll-free number: 1-877-CTP-1373
- Send an e-mail: CTPCompliance@FDA.hhs.gov

COLLABORATION



If you experience a problem with a tobacco product, such as an unexpected health or safety issue, you may report it to FDA's Safety Reporting Portal

(Ex. Damage or defective products, product use that resulted in harm or damage to property, unexpected harms when being exposed to tobacco products)

[Safety Reporting Portal for Tobacco Products | FDA](#)

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

Reports You Can Submit Through this Portal

FDA safety issues involving:

- Marketed human drug and biologics
- Human or animal reportable foods
- Animal drugs
- Animal foods
- Tobacco products
- Dietary supplements

Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- An applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any marketed drug

HOW TO CONTACT US?

For questions, technical assistance, or guidance finding the right resources, you can contact OSBA at:

E-mail: SmallBiz.Tobacco@fda.hhs.gov

Phone: 1-877-287-1373 (Monday-Friday, 9:00 a.m. - 4:00 p.m. ET)

Mail: FDA/CTP Office of Compliance and Enforcement
Document Control Center
Building 71, Room G335
10903 New Hampshire Ave.
Silver Spring, MD 20993