

TOBACCO REGISTRATION AND PRODUCT LISTING UPDATES

Office of Compliance and Enforcement

CENTER FOR TOBACCO PRODUCTS

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

AGENDA



- Overview of Section 905 of the FD&C Act
- (New) Tobacco Registration and Listing Module Next Generation (TRLM NG) system
- Who must register their establishments?
- When to register and when to update an establishment's registration and product listing in TRLM NG?
- Types Of Updates To Include In Biannual Updates - 905(i)
- How to update an establishment's registration and product listing?

SECTION 905 OF THE FD&C ACT



- Section 905(a)(1) **Manufacture, Preparation, Compounding, or Processing**. The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.
- Section 905(b) requires owners and operators of establishments in any U.S. state or territory (or D.C.) engaged in the manufacturing, preparing, compounding, or processing of a tobacco product to register **on or before December 31st of each year**.
- Section 905(i)(3) of the Act requires that any changes in the product list be submitted biannually, once during **June** and once during **December**.

THE NEW TRLM NG SYSTEM

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(j)(3) 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](#)

Returning User? Sign in.

- 1 Your FURLS email is now your Tobacco Registration and Listing Module Next Generation (TRLM NG) username. Please click the [Account Activation](#) link to proceed the Account Activation page.

Username (This is your email)

Password

[Forgot Password?](#)

Please acknowledge the following

[Expand](#)

Under 18 U.S.C. 100, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I have read and understood this message

[Sign In](#)

THE NEW TRLM NG SYSTEM



Industry Users can:

- Review guidance on FDA registration and product listing requirements;
- Register establishments, products, and material files with the FDA; and
- Update registration information annually and product listing changes biannually to comply with statutory requirements.

How to access TRLM NG:

- <https://trlm-ng-industry.fda.gov>

WHO MUST REGISTER



- Every person who owns or operates any **domestic** establishment engaged in manufacturing, preparing, compounding, or processing regulated tobacco products must register under section 905(b) of the FD&C Act, and every registrant must file a list of its regulated tobacco products in accordance with section 905(i) of the FD&C Act.
- An owner or operator may authorize a third-party agent to register their establishment and submit product listing information on its behalf. Establishment registration and product listing requirements currently apply only to those persons who own or operate domestic establishments engaged in manufacturing, preparing, compounding, or processing tobacco products; an importer who does not own or operate such an establishment is not subject to the requirements of section 905(b) or section 905(i) of the FD&C Act.

WHEN TO REGISTER AND WHEN TO UPDATE AN ESTABLISHMENT'S REGISTRATION AND PRODUCT LISTING IN TRLM NG?



- A domestic establishment must register when it first engages in the manufacturing of a tobacco product.
- We request that a firm update its registration when it no longer engages in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, including repackaging and relabeling of tobacco products.
- For example:
 - Out of business;
 - Now solely a retail establishment; or
 - An importer who is not conducting manufacturing activities outlined in 905(a)(1).
 - Brand owner who is not conducting manufacturing activities outlined in 905(a)(1).

TYPES OF UPDATES TO INCLUDE IN BIENNIAL UPDATES - 905(i)



- A tobacco product is introduced into commercial distribution that was not included in a previous product list.
- A manufactured tobacco product is discontinued from commercial distribution since the last report.
- A tobacco product was marked as discontinued in a previous report, and manufacturing and commercial distribution of the product has since resumed.
- Any material change in any information previously submitted.

HOW TO UPDATE A REGISTRATION AND PRODUCT LISTING



- Electronic submission system: TRLM NG
 - Link to TRLM NG: <https://trlm-ng-industry.fda.gov>
- Paper submission: FDA Form 3741 and 3741(a)

HELPFUL RESOURCES



- **Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments:**
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments>.
- **The “Need help” page:** <https://trlm-ng-industry.fda.gov/help>
- **For Registration and Listing questions:** CTPRegistrationandListing@fda.hhs.gov
- **Webinar:** [Registration And Product Listing Requirements For Domestic Establishments](#)

THANK YOU

If you have any TRLM NG questions, you can contact us at:

E-Mail: AskCTP@fda.hhs.gov

Phone: 1-877-CTP-1373

For other questions, technical assistance, or guidance finding the right resources, you can contact the Office of Small Business Assistance (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