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Center for Tobacco Products (CTP) Tobacco Registration and Listing Module - Next Generation (TRLM-NG)

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Disclaimer:

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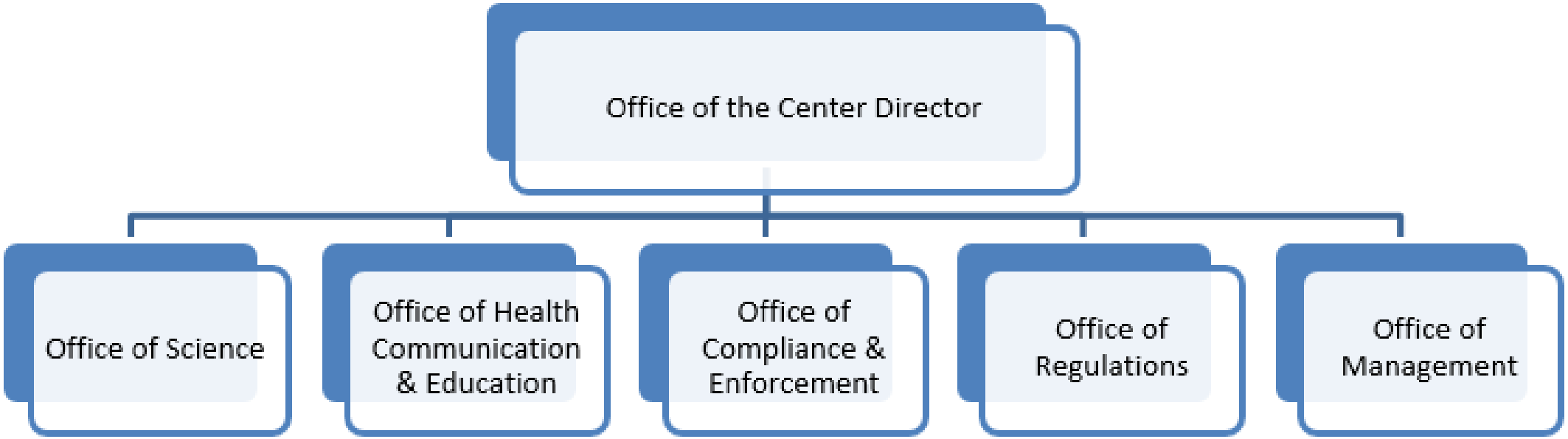
Agenda:

- CTP and OCE Overview
- Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)
- Registration and Listing Requirements
- TRLM NG Overview
- Infrastructure and Data Sharing
- Helpful Resources

FDA's Center for Tobacco Products (CTP)



FDA Center for Tobacco Products

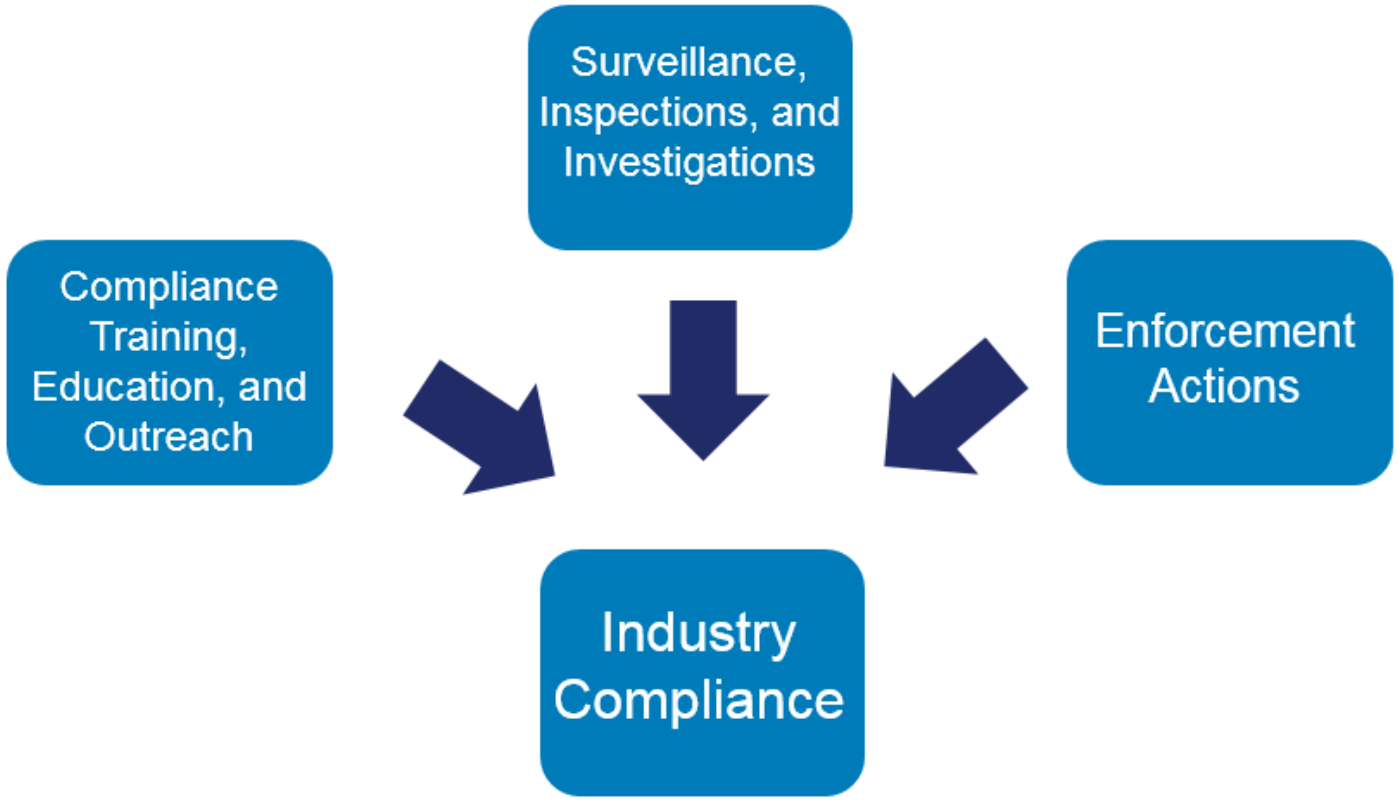
Our Vision

- To make tobacco-related disease and death part of America's past, not America's future, and, by doing so, ensure a healthier life for every family.

Our Mission

- To protect Americans from tobacco-related disease and death by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

FDA CTP Office of Compliance (OCE)



OCE monitors retailer, manufacturer, importer, and distributor compliance with FDA tobacco laws and regulations and takes appropriate enforcement action when violations are found.

Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)

- The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), was enacted on June 22, 2009, amending the Federal Food, Drug & Cosmetic Act (FD&C Act) and providing FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health.

- On May 10, 2016, FDA issued the deeming rule extending FDA's tobacco product authority to all products, other than accessories of newly deemed products, that meet the statutory definition of tobacco product, including, for example, electronic nicotine delivery systems (ENDS), cigars, hookah tobacco, and pipe tobacco.

- On March 15, 2022, the definition of "tobacco product" in Section 201 (rr) of the FD&C Act was amended to include products containing nicotine that is not made or derived from tobacco, or containing nicotine from any source, which became immediately subject to FDA's tobacco product authorities under Chapter IX of the FD&C Act.

Overview of FDA's Authority Over Tobacco Products

Examples of Tobacco Products Regulated under the Tobacco Control Act (2009)	Examples of Tobacco Products Regulated Under the Deeming Rule (2016)	Examples of Non-Tobacco Nicotine (NTN) Tobacco Products Regulated Under Expanded Authority (2022)
• Cigarettes • Cigarette tobacco • Roll-Your-Own tobacco • Smokeless tobacco *This includes the components, parts, and accessories of these products*	• ENDS* • Pipe tobacco • Cigars • Hookah/Waterpipe tobacco • E-liquid • Dissolvable products not already regulated by FDA • Future tobacco products *This includes the components and parts of these products, but not their accessories*	• Products with nicotine derived from other sources (other than nicotine made or derived from tobacco) • Synthetic Nicotine

**ENDS=Electronic Nicotine Delivery System*

Section 905 of the FD&C Act: Registration and Listing Requirements

- **WHO**: Section 905(b) requires that "*every person* who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" register with FDA the name, places of business, and all establishments engaged in these activities owned or operated by that person.
  - Section 905(a)(1), describes 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.
- **WHEN**: Section 905(c) requires every person upon first engaging in the manufacturing of a tobacco product in any domestic establishment owned or operated by that person to *immediately* register. **Following the initial registration, every person must register annually by December 31st of each year.**
- **WHAT**: Section 905(i)(1) requires that all registrants "shall, at the time of registration… file with [FDA] a list of *all tobacco products* which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with *certain accompanying information*, including *all labeling*. In addition, section 905(i)(3) requires that any change in the product list be submitted to FDA biannually, once during June and once during December.

Background of TRLM NG and Impact of The Deeming Rule

- In 2016, The Deeming Rule extended FDA's authority to all products that meet the statutory definition of tobacco product.
- Hundreds of millions of products were listed, including all labeling and other information, over a short period of time, causing significant issues with processing submissions using the previous FDA systems.
- In 2020, CTP implemented a scalable tobacco registration system to handle large data processing and storage system
  - ***Tobacco Registration and Listing Module Next Generation (TRLM NG)***

What Is TRLM NG?

The Tobacco Registration and Listing Module Next Generation (TRLM NG) replaced the legacy FURLS TRLM systems as CTPs application for industry to register and certify tobacco and vape establishment and product information.

TRLM NG includes three modules: 1) Industry module for industry users; 2) Internal module for FDA users; and 3) Registration and Listing (R&L) for public users to query publicly available information.

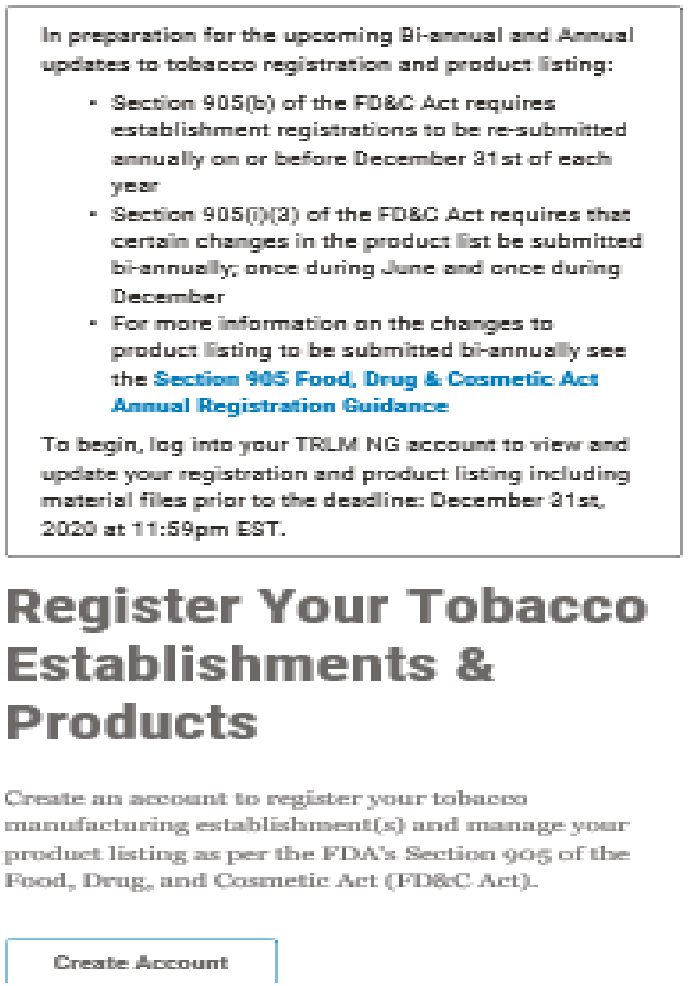
TRLM NG is a cloud native application built on the AWS GovCloud FedRAMP environment. The modernized TRLM NG now handles:

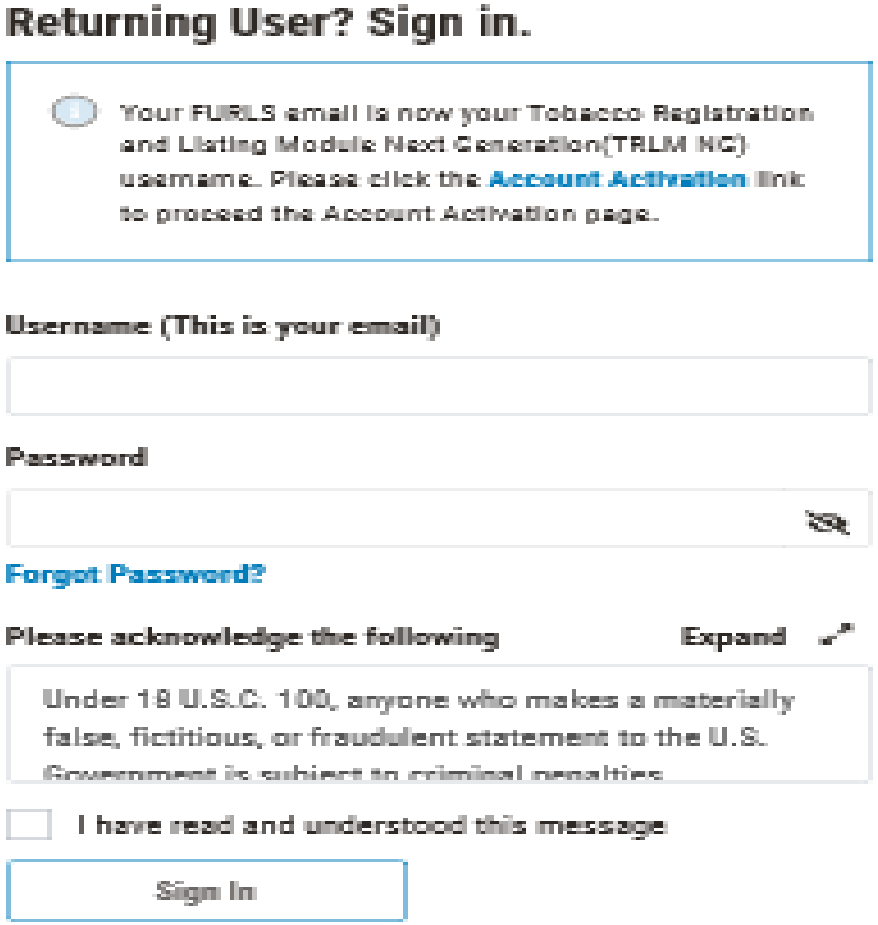
- 17,000 domestic and international users
- 8 billion records and 800 million related document files (structured or unstructured)
- Has a 10+ year lifespan
- Influxes of large number of concurrent users (autoscaling)

TRLM NG also improved the following:

- Enhanced user experience (user interface & system performance) including automated address validation and data verification prior to certification
- Built-in system monitoring and alerts, along with enhanced reporting
- Automatic backup data repository and disaster recovery through AWS availability zones

TRLM NG


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)(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.
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.
I have read and understood this message
Sign In

TRLM NG

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

TRLM NG Modules High-Level Overview

TRLM NG includes three modules:

1. Industry Module for Industry Users with a TRLM NG account to register their establishments and products
2. Internal Module for FDA Users to review tobacco registration data
3. R&L Public Website which shares data with external parties and allows for public users to search active establishments and products from TRLM NG

TRLM NG Industry Users

FDA Internal Users

Public Users

TRLM NG: Note Regarding Public Site

- Registration and listing information is provided and periodically updated by regulated entities. FDA has posted the submitted information publicly as a means of providing public access to the information, which is required by Section 905(f) of the Tobacco Control Act, and as a service to interested stakeholders.
- FDA is currently working to improve the accuracy and completeness of the information submitted by regulated entities. FDA is not vouching for the accuracy of any particular entry; the information is posted as received by industry. For example, FDA cannot prevent the submission of duplicate, inaccurate, and/or unnecessary entries, at this time.

Modernizing Services at CTP

The Tobacco Registration and Listing Module Next Generation (TRLM NG) application infrastructure has been strengthened by implementing modern cloud engineering architecture components.

TRLM NG provides the following benefits:

- Enhanced user experience through in-application guidance and system performance
- Enhanced upload speeds for bulk products and material files
- Enhanced data validation and integrity specifically around address standardization and product data integrity resulting in less duplicate data in the system
- Built-in application monitoring and alerts
- Robust recovery plans to keep the system up 24/7/365

TRLM NG Auto- Scaling to Handle Large Volumes of Data and Registrations

TRLM NG provides the following benefits:

- Enhanced user experience through in-application guidance and system performance
- Developed macro-enabled spreadsheet for bulk product validation and data integrity
- Enhanced tobacco product data to include attributes to help CTP gather more data on products
- Enhanced upload speeds for bulk products and material files
- Enhanced data validation and integrity specifically around address standardization and product data integrity resulting in less duplicate data in the system
- Autoscaling for potential influx of records and/or users to the system based on any regulatory changes

Going Forward

- TRLM NG will continue to evolve as CTP's registration and listing support system as new CTP modernization initiatives deliver new feature functionality and data services

- Future improvements include automating more business workflows, enhancing current FDA system integrations, implementation of AI/ML solutions, advanced analytics and archiving, and improving data standardization across the Center for dashboards and reporting

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 for your time and attention!

Questions?