

Presented by Lillian Ortega Office of Compliance and Enforcement

May 2018

**CENTER FOR TOBACCO PRODUCTS** 

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



- 1. If you have not made changes to the information you previously submitted with your tobacco product listings, you do not have resubmit that information.
- 2. You must submit updates to your tobacco product listings only if you have made certain changes to those listings or introduced additional tobacco products into commercial distribution.



### Report These Updates to FDA:

- You have introduced a tobacco product into commercial distribution and you did not include that product in a previous submission, or
- You discontinued manufacturing a tobacco product for commercial distribution since your last listing, or
- You listed a tobacco product as discontinued in a previous listing, but you have since resumed manufacturing that tobacco product for commercial distribution, or
- You have made any material change to any information you previously submitted.



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 Example: Manufacturer has changed its deemed tobacco product's label to include the nicotine addictiveness warning statement:

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

- The requirement to include the addictiveness warning statement to product packages and advertisements applies to cigarette tobacco, roll-your-own tobacco, and covered tobacco products (other than cigars and those covered tobacco products that do not contain nicotine).
- Manufacturers cannot manufacture such products with non-compliant packages beginning August 10, 2018, and cannot distribute such products beginning September 11, 2018, irrespective of the date of manufacture.





### **FDA Industry Systems**



09/19/2017 See <u>FDA published the revised guidance</u>, <u>Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments. Click here for details.</u>

09/12/2017 See Information regarding Tobacco Registration and Product Listing for manufacturers impacted by recent natural disasters. Click here for details.

# Existing account holders, enter your account ID & password. Account ID Password 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. I understand. Forgot Account ID Forgot Password

### **Getting Started**

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page.

If you already have an account, enter your account ID and password.

**WARNING:** 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, and 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.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

If you have Tobacco Registration and Product List (TRLM) specific questions, please email FDA at CTPRegistrationandListing@fda.hhs.gov and the Registration and Listing staff can assist with



CTPRegistrationandListing@fda.hhs.gov

Office of Small Business Assistance

- Smallbiz.Tobacco@fda.hhs.gov
- 1-877-287-1373
- (9am EST-4pm EST)



- Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments
- Tobacco Registration and Product Listing (TRLM) Instructions
- FDA's Deeming Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products (search for "deeming" on the CTP website <a href="www.fda.gov/tobaccoproducts/">www.fda.gov/tobaccoproducts/</a>)
- <u>Using the Tobacco Registration and Listing Module of FURLS Tips and Recent Enhancements</u> Webinar
- Registration And Product Listing Requirements For Domestic Establishments Webinar

# THE END

