

USING THE TOBACCO REGISTRATION AND LISTING SYSTEM – TIPS AND RECENT ENHANCEMENTS

Presented by
Lillian Ortega
Deputy Director
Division of Enforcement and Manufacturing
OCE, CTP, FDA
September 2017

CENTER FOR TOBACCO PRODUCTS

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

GUIDANCE ON EXTENSION OF CERTAIN DEEMING COMPLIANCE DATES



- In May 2017, FDA issued a guidance extending certain future compliance deadlines for requirements under the final deeming rule.
- This extension applies to the Establishment Registration and Product Listing provisions.
- For entities engaged in the manufacture, preparation, compounding, or processing of tobacco products in the U.S. prior to August 8, 2016, and continuing operations after August 8, 2016, the new compliance date to register and submit product listings is September 30, 2017.

- Section 905(b) requires owners and operators of establishments engaged in the manufacturing of a tobacco product to register on or before December 31st of each year.
- Section 905(i)(1) requires, at the time of first registration, a registrant to submit a list of all tobacco products manufactured by the registrant for commercial distribution.
- Section 905(i)(3) requires that certain changes to your product list be reported twice per year - in June and December.

REGISTRATION AND PRODUCT LISTING - TIPS



- TRLM – Tobacco Registration and Listing Module of the FDA Unified Registration and Listing System (FURLS)
- FEI – FDA Establishment Identification Number
- It is recommended you complete all the fields, including contact information, in TRLM. This will assist FDA with contacting you in case there are questions about your submission.
- PO Boxes are not an acceptable establishment location for entry into TRLM.
- Include the address of the physical location of the manufacturing site and the legal name.

REGISTRATION AND PRODUCT LISTING - TIPS



- Deletions of data submitted to TRLM is not permitted.
- Use the “inactivate tobacco products” process if you are no longer marketing and distributing a tobacco product.
- Refer to the TRLM help guide for instructions. Available here: [https://www.fda.gov/downloads/TobaccoProducts/Labeling/Rule sRegulationsGuidance/UCM456130.pdf](https://www.fda.gov/downloads/TobaccoProducts/Labeling/Rule%20RegulationsGuidance/UCM456130.pdf)
- Product Listings can be duplicated or moved in TRLM to another manufacturer only if both establishments were registered under the same Account ID.

REGISTRATION AND PRODUCT LISTING - TIPS



- Templates in the form of Excel spreadsheets are available to use as part of the product listing submission process.
- Spreadsheets with up to 800 rows are uploaded and processed instantly.
- Spreadsheets with 801-250,000 rows are processed offline.
- Please verify you have the most current version of the spreadsheet. Modifying a spreadsheet (i.e. deleting a header or column) will result in an error message.
- Complete all required columns (noted with an *) prior to attempting an upload into TRLM.

REGISTRATION AND PRODUCT LISTING - TIPS



- Use TRLM to submit tobacco registration and product listing information.
- eSubmitter is used to submit ingredient listing information.

REGISTRATION AND PRODUCT LISTING - TIPS



- Foreign manufacturers are currently not required to register and submit product listings provided they do not own or operate a domestic establishment engaged in the manufacture, preparation, compounding or processing of a tobacco product.
- Importers are not required to register and submit product listings unless they also own or operate a domestic establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product.
- An importer who relabels an imported tobacco product in a domestic establishment would be required to register and list.
- Establishments solely performing retailer activities (selling tobacco products to individuals for personal consumption) do not register.

REGISTRATION AND PRODUCT LISTING - TIPS



- Guidance – Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule:

<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>

- FAQ for FURLS TRLM:

https://www.access.fda.gov/access_images/FURLS_TRLM_QandA.pdf

- Manufacturer webpage:

<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/default.htm>

- FURLS TRLM Additional Information Page:

<https://www.access.fda.gov/trlm/additionalResources-flow.htm?execution=e2s1>

- Small Business Assistance for Tobacco Products:

<https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/SmallBusiness/default.htm>

- Since Winter 2016, there have been multiple enhancements of the TRLM system to streamline the registration and product listing process.
- A list of enhancement that have been made can be found here:
https://www.access.fda.gov/access_images/Tobacco%20Registration%20and%20Listing%20Module.pdf

- Until you submit all of the required information in the TRLM system, your submission will be in DRAFT status for up to 60 calendar days.
- If your submission is in draft status for 50 calendar days, the system will send you an email reminder that your submission is approaching the 60 calendar days draft threshold.
- If you require more time to complete your submission, a firm may request a draft submission status be extended.
- Send email to CTPRegistrationandListing@fda.hhs.gov and include your Account ID in your request.
- A granted request for an extension of a draft submission will not change the current compliance deadlines.

- Decoupling the registration submission from the product listing submission, including the submission of advertising, labeling, and/or consumer information.
- With decoupling, the system will allow you to submit and update your registration information and add/associate product materials files at a later date (statutory requirements and compliance deadlines still apply).

Video Tutorials

- Accessing TRLM and Creating a New Account
- Registering a Tobacco Product Establishment and Associating a Product Listing
- Updating an Existing Product Listing
- Uploading Multiple Material Files or Larger Sized Material Files
- Associate Advertising Files to Multiple Products

<https://www.fda.gov/tobaccoproducts/guidancecompliance regulatoryinformation/manufacturing/ucm386651.htm>

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*) at <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm189539.htm>

- Product listing for some tobacco products may result in numerous labeling submissions.
- FDA does not at this time intend to enforce the requirements that owners and operators submit the labeling for each individual listed tobacco product WHEN the registrant submits information that represents the labeling for a selected line of products.
- See guidance for an example.
- Send questions to CTPRegistrationandListing@fda.hhs.gov and include “registration and listing labeling submissions” in subject line.

THE END

FDA