



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA-2015-D-2325]

Tobacco Product Master Files; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Tobacco Product Master Files." This guidance provides recommendations to industry on tobacco product master files (TPMFs). TPMFs are voluntary submissions used to permit the person that owns the TPMF to authorize other parties to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose that information to the authorized parties. Parties that obtain a right of reference from a TPMF owner may reference information in a TPMF that the TPMF owner does not want to make public, but that the other party would otherwise need to develop on its own to make a complete submission to FDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-2325 for "Tobacco Product Master Files; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable

at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Nathan Mease, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000, 1-877-287-1373, email: AskCTP@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Tobacco Product Master Files." This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because immediate implementation of the guidance is needed to assist in addressing a public health issue. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

The guidance document provides recommendations to industry on TPMFs. TPMFs are voluntary submissions to FDA that contain information about a tobacco product. TPMFs are used to permit the person who owns the TPMF (TPMF owner) to authorize other persons to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose that information to other persons. Authorization to reference a TPMF may be especially useful to manufacturers or applicants preparing premarket submissions, such as substantial equivalence reports, for new tobacco products. Other parties who obtain a right of reference from a TPMF owner can reference information in a TPMF that the TPMF owner does not want to make public, but that the other party would otherwise need to develop on its own to make a complete submission to FDA. The guidance provides information on how to establish a TPMF, including what to submit and where to submit the TPMF.

The guidance represents the current thinking of FDA on TPMFs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to collections of information described in FDA's final rule on Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. The collections of information in the final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has published an analysis of the information

collection provisions elsewhere in this issue of the Federal Register and has submitted them for OMB approval.

This guidance also refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501-3520). The collections of information in section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been approved under OMB control number 0910-0673; the collections of information in sections 904(a)(1), (c) and 905(b), (c), (d), (h), (i) of the FD&C Act have been approved under OMB control number 0910-0650; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910-0654; the collections of information in 21 CFR 1107.1(b) and (c), 21 CFR 25.40, and section 905(j)(1)(A)(ii) of the FD&C Act have been approved under OMB control number 0910-0684; the collections of information in sections 904(a)(3) and 904(c)(1) of the FD&C Act have been approved under OMB control number 0910-0732; and the collections of information in section 910 have been approved under OMB control number 0910-0775.

### III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or

<http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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