

Tobacco Product Master Files

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with Docket No. FDA-2015-D-2325.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at

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

You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides recommendations to industry on tobacco product master files (TPMFs). TPMFs are used to permit the person that 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. These files typically contain trade secret and/or confidential commercial information that the TPMF owner does not wish to make public. Authorization to reference a TPMF may be especially useful to manufacturers or applicants preparing premarket submissions for tobacco products. Other parties that 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. For example, a filter manufacturer might provide another person a right of reference to its TPMF which contains the full listing of materials, ingredients, and composition information of the filter. This information could then be used by the other person to support requirements in a premarket application for a finished cigarette that uses the filter as a component.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance was prepared by the Office of Science and Office of Regulations in the Center for Tobacco Products at FDA.

Contains Nonbinding Recommendations

II. DISCUSSION

A. How to establish a master file

1. What to submit. For purposes of this guidance, a TPMF is a voluntary submission to the FDA that contains information about a tobacco product (including but not limited to materials, parts, components and accessories of tobacco products, or the facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of tobacco products), that the manufacturer does not want to share with other persons. To establish a TPMF, FDA recommends that the following information be submitted to FDA, in English, and with the pages numbered sequentially:

- A cover letter that includes:
 - (i) A statement that the information is being submitted as a TPMF;
 - (ii) A brief description of the content of the TPMF;
 - (iii) The name, mailing address, email address, and phone number of the TPMF owner (the person establishing and holding the TPMF);
 - a. If an authorized representative can grant a right of reference to the TPMF on behalf of the owner and will communicate on behalf of the owner, the name, mailing address, email address, and phone number of that individual;
 - b. If the TPMF owner or authorized representative does not reside in or have a place of business the United States, the name, mailing address, email address, and phone number of a U.S. agent;
- A current table of contents;
- The information that is to be made part of the TPMF;
- A list of each person currently authorized to reference the TPMF (including name, mailing address, email address, and phone number); and
- Identification of any limitations on each authorization (e.g., if the TPMF owner is authorizing others to use only certain sections and, if so, identification of those sections).

2. Where to submit. The TPMF owner (or authorized agent) should submit this information to FDA, via the FDA Electronic Submission Gateway (<http://fda.gov/esg>) using eSubmitter or mail the information to the following address:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

B. Additional considerations for TPMF owners in maintaining TPMF submissions

1. Updates to information. If any information in the TPMF changes, the TPMF owner should update the TPMF, identifying the sections that have changed.

Contains Nonbinding Recommendations

2. *Closure of a TPMF.* If a TPMF owner wishes to close its TPMF, the TPMF owner should notify the FDA in writing and include, in the notification, the reason for requesting closure of the file and the date the TPMF should be closed. Additionally, it is recommended that the TPMF owner notify all persons currently authorized to reference the TPMF of the closure, as once closed the TPMF will no longer be available for reference.

C. How other persons can use a TPMF

The TPMF owner may, in writing, grant authorization to reference the TPMF to other persons, including applicants and manufacturers. The written authorization should describe the specific sections of the TPMF to which the TPMF owner is authorizing right of reference. Persons who have been granted written authorization to reference the TPMF, or a portion thereof, may rely on the information in the TPMF to support a submission to FDA without the TPMF owner having to disclose this information to them. If there are any questions about the content of the TPMF, the other person should discuss the questions with the TPMF owner. The ability to refer to a TPMF can be helpful to other persons that are preparing premarket applications, such as substantial equivalence reports or premarket tobacco product applications.

D. FDA's role

1. *Review of a TPMF.* FDA does not intend to conduct a scientific review of a TPMF at the time of its submission, and establishment of a TPMF should not be construed as a conclusion regarding its contents by FDA. Instead, FDA typically reviews the information in a TPMF only in the context of reviewing a particular submission, e.g., when an authorized applicant or manufacturer references material in a TPMF in its application or submission.

2. *FDA Initiation of TPMF Closure.* FDA intends to begin a closure process if the TPMF has not been referenced within three years and there have been no updates during this time. Prior to closure of any TPMF, FDA intends to issue a notification letter to the TPMF owner of the intent to close. The TPMF owner may respond to the notification letter within the time period specified to keep the TPMF active.