Guidance for Industry

Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007 (Revised)*

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-2011-D-0125.

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, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, Maryland, 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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See additional PRA statement in Section VI of this guidance.

***** This is a revision to the first edition of this guidance, which FDA issued in September 2014. A summary of the revisions are listed at the end of the guidance.

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Contains Nonbinding Recommendations

Guidance for Industry[1]

Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance includes a description of the types of evidence recommended to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance also includes definitions and administrative information, such as who may submit a request for a pre-existing status review and how to submit a request.

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.

II. DEFINITIONS

This section provides the definitions of certain terms used in this guidance document.

A. What is a tobacco product?

A *tobacco product* is any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

[1] This guidance was prepared by the Office of Compliance and Enforcement and the Office of Regulations in the Center for Tobacco Products at FDA.

The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act (FD&C Act) is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if the food contains no nicotine, or no more than trace amounts of naturally occurring nicotine (section 201(rr) of FD&C Act).[2]

The term is not limited to products containing tobacco or nicotine, but also includes components, parts, or accessories of tobacco products, whether they are sold for further manufacturing or for consumer use. For example, tobacco, papers, and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

B. What is a new tobacco product?

A *new tobacco product* is defined in section 910(a)(1) of the FD&C Act[3] as:

> (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
>
> (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

In general, a tobacco product manufacturer must obtain an order under section 910(c)(1)(A)(i) (order after review of a premarket application) before the manufacturer may introduce a new tobacco product into interstate commerce (section 910 of the FD&C Act). An order under section 910(c)(1)(A)(i) is not required, however:

- if a manufacturer submits a substantial equivalence report under section 905(j) of the FD&C Act[4] (a 905(j) report) and obtains an order under section 910(a)(2)(A)(i); or
- if FDA has granted a substantial equivalence exemption request submitted under 21 CFR 1107.1 and the manufacturer submits the required report under section 905(j).

[2] 21 U.S.C. 321(rr)
[3] 21 U.S.C. 387j(a)(1)
[4] 21 U.S.C. 387e(j)

C. What is a pre-existing tobacco product?

A pre-existing tobacco product refers to a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007 (21 CFR 1100.202). Pre-existing tobacco products are **not** considered new tobacco products and thus are not subject to the premarket requirements of the FD&C Act (section 910 of the FD&C Act). Commercially marketed "means selling or offering for sale a tobacco product in the United States to consumers or to any person for the eventual purchase by consumers in the United States." (21 CFR 1100.202).

D. How is "as of" defined?

We interpret the phrase "as of" February 15, 2007, as meaning that the tobacco product was commercially marketed (including those products in test markets) in the United States **on** February 15, 2007. If your tobacco product had been commercially marketed in the United States before February 15, 2007, but was not commercially marketed on that date, it is not a pre-existing product and may not be commercially marketed unless you comply with the premarket requirements of section 910 of the FD&C Act and obtain a marketing order. Section IV.B describes how you can demonstrate that a tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.

III. ADMINISTRATIVE INFORMATION

A. Who may request a pre-existing status review?

If you believe that your tobacco product should be considered a pre-existing tobacco product and would like an Agency determination on the status of your product, you may submit a request for review as described in section III.B below. Submitting a tobacco product for pre-existing status review is voluntary and not required under the FD&C Act.

At this time, FDA intends to limit its review of pre-existing status to finished, regulated tobacco products. These finished, regulated tobacco products include the tobacco products named in section 901(b) of the FD&C Act (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and products containing nicotine not made or derived from tobacco) and tobacco products deemed by regulation to be regulated under Chapter IX, as well as the component parts of regulated tobacco products sold or distributed for consumer use (e.g., cigarette rolling papers, filters, or filter tubes sold separately to consumers or as part of kits). FDA does not intend to review pre-existing status for component parts of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products because at this time the Agency does not intend to enforce the requirements of sections 910 and 905(j) of the FD&C Act for these components.

B. How should a request for a pre-existing status review be submitted to FDA?

For the purposes of this guidance, a submission requesting a pre-existing status review is referred to as a *pre-existing tobacco product submission*. Each tobacco product should be submitted in a separate pre-existing tobacco product submission.[5] Pre-existing tobacco product submissions can be submitted electronically via the FDA's Electronic Submissions Gateway (ESG) [6] using FDA's eSubmitter tool.[7] Although electronic submission is not required, FDA strongly encourages electronic submission for efficient and timely data submission and management. Alternatively, submissions can be mailed to:

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

C. How will FDA review the pre-existing tobacco product submission?

FDA will review the pre-existing tobacco product submission to determine whether the tobacco product is a pre-existing tobacco product, i.e., a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. FDA will notify you of its determination in writing. If FDA is unable to determine the pre-existing status of your product, the Agency may contact you to request further information.

IV. RECOMMENDED CONTENT OF A REQUEST

A. Description of the tobacco product

FDA recommends that you specifically identify the product (e.g., name) and provide a brief description of the tobacco product that will allow FDA to review your request in context. For example, the description could include a list of components that comprise the product, a basic description of the materials, and how the product is used by the consumer. In addition, to better assist our review of your request, the description should include a legible photograph or schematic diagram of the tobacco product.

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[5] These procedures pertain specifically to pre-existing tobacco product submissions. The procedures related to pre-existing tobacco product evidence submitted as part of a 905(j) report are not within the scope of this guidance document.

[6] The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks. Once approved, the user can send all submissions to CTP using the eSubmitter tool and FDA ESG. Instructions on obtaining an ESG account are available at https://www.fda.gov/industry/electronic-submissions-gateway/create-esg-account.

[7] The FDA eSubmitter tool is an electronic application designed to streamline the process for regulatory submissions. Users of the eSubmitter tool first download and install the computer application and then enter all data. The eSubmitter tool is available at https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions

B. Evidence demonstrating the pre-existing status of the tobacco product

FDA recommends that you provide adequate information to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. As stated in section II.D, we interpret "as of" to mean "on." Accordingly, the information submitted should demonstrate (individually or collectively) that the tobacco product was commercially marketed in the United States on February 15, 2007. If you cannot provide documentation specifically dated on February 15, 2007, FDA suggests you provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007.

Examples of such information may include, but are not limited to, the following:

- dated copies of advertisements
- dated catalog pages
- dated promotional material
- dated trade publications
- dated bills of lading
- dated freight bills
- dated waybills
- dated invoices
- dated purchase orders
- dated customer receipts
- dated manufacturing documents
- dated distributor or retailer inventory lists
- any other document you believe demonstrates that the tobacco product was commercially marketed in the United States as of February 15, 2007

FDA will consider and evaluate all of the information provided on a case-by-case basis.

V. PUBLIC AVAILABILITY OF INFORMATION

Your pre-existing tobacco product submission may include nonpublic trade secret or confidential commercial information. Several laws govern the confidentiality of information submitted under the FD&C Act, including section 906(c) of the FD&C Act (21 U.S.C. 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's regulations implementing these laws. FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR part 20.

VI. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 5 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0775. To find the current expiration date, search for this OMB control number at https://www.reginfo.gov.

VII. DOCUMENT HISTORY

March 2023— Guidance updated to reflect statutory amendments made by the Consolidated Appropriations Act, 2022 (Pub. L. 117-103). Among other things, the legislation amends the definition of "tobacco product" in section 201(rr) of FD&C Act to include products "containing nicotine from any source.

- **Section III—**Edits to reflect amendments to 201(rr) and 901(b) of the FD&C Act.

MONTH 20XX – Revisions included the following:

- Replaced "grandfathered" with "pre-existing" / "pre-existing tobacco product" to be consistent with 21 CFR 1100.202.
- Clarifying and editorial changes to promote consistency throughout our guidances and with the 21 CFR part 1107.