SUBCHAPTER K—TOBACCO PRODUCTS

PART 1100—GENERAL

Subpart A—Tobacco Products Subject to FDA Authority

Subpart B [Reserved]

Subpart C—Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AUTHORITY: 21 U.S.C. 371, 374, 387a(b), 387e, 387i; Pub. L. 117–103, 136 Stat. 49.

SOURCE: 81 FR 29102, May 10, 2016, unless otherwise noted.

Subpart A—Tobacco Products Subject to FDA Authority

§ 1100.1 Scope.

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any tobacco product containing nicotine not made or derived from tobacco, FDA deems all other products meeting the definition of *tobacco product* under section 201(rr) of the Federal Food, Drug, and Cosmetic Act, except accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

[88 FR 16552, Mar. 20, 2023]

§ 1100.2 Requirements.

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any tobacco product containing nicotine not made or derived from tobacco are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

[81 FR 29102, May 10, 2016, as amended at 88 FR 16552, Mar. 20, 2023]

§ 1100.3 Definitions.

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Package or *packaging* means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

Tobacco product, as stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part:

(1) Means 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); and

(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act; a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act; a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act; or a food under 201(f) of the Federal Food, Drug, and Cosmetic Act if such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

[81 FR 29102, May 10, 2016, as amended at 88 FR 16552, Mar. 20, 2023]

§ 1100.5 Exclusion from tobacco regulation.

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

(a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction (*e.g.,* smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms;

(b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

[82 FR 2217, Jan. 9, 2017]

Subpart B [Reserved]

Subpart C—Maintenance of Records Demonstrating That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.

SOURCE: 86 FR 55411, Oct. 4, 2021, unless otherwise noted.

§ 1100.200 Purpose and scope.

This subpart sets out requirements under the Federal Food, Drug, and Cosmetic Act for the maintenance of records by tobacco product manufacturers that introduce a Pre-Existing Tobacco Product, or deliver it for introduction, into interstate commerce.

§ 1100.202 Definitions.

For the purposes of this subpart:

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.

Pre-Existing Tobacco Product means a tobacco product (including those products in test markets) that was commercially marketed in the United States as of February 15, 2007. A Pre-Existing Tobacco Product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

Tobacco product means 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). The term ''tobacco product'' does not mean an article that under the Federal Food, Drug, and Cosmetic 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 such article contains no nicotine or no more than trace amounts of naturally occurring nicotine.

Tobacco product manufacturer means any person, including any repacker or relabeler, who—

(1) Manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(2) Imports a finished tobacco product for sale or distribution in the United States.

[81 FR 29102, May 10, 2016, as amended at 88 FR 16552, Mar. 20, 2023]

§ 1100.204 Recordkeeping requirements.

(i) Any tobacco product manufacturer that introduces a Pre-Existing Tobacco Product, or delivers it for introduction, into interstate commerce must maintain records that demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007, as described in this subpart. These records may include items such as:

(A) Dated copies of advertisements;

(B) Dated catalog pages;

(C) Dated promotional material;

(D) Dated trade publications;

(E) Dated bills of lading;

(F) Dated freight bills;

(G) Dated waybills;

(H) Dated invoices;

(I) Dated purchase orders;

(J) Dated customer receipts;

(K) Dated manufacturing documents;

(L) Dated distributor or retailer inventory lists; or

(M) Any other dated document that demonstrates that the tobacco product was commercially marketed in the United States as of February 15, 2007.

(ii) All records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. Documents that have been translated from another language into English (*e.g.*, advertisements written in a language other than English) must be accompanied by the original language version of the document, a signed statement by an authorized representative of the manufacturer certifying that the English language translation is complete and accurate, and a brief statement of the qualifications of the person that made the translation.

(iii) All records required by this subpart must be retained for a period of not less than 4 years after the date either FDA makes a determination that the product is a Pre-Existing Tobacco Product, or the tobacco product manufacturer permanently ceases the introduction or delivery for introduction into interstate commerce of the tobacco product, whichever occurs sooner.

PART 1105—GENERAL

AUTHORITY: 21 U.S.C. 371(a), 387e, 387j, and 387k.

SOURCE: 81 FR 95869, Dec. 29, 2016, unless otherwise noted.

Subpart A—General Submission Requirements

§ 1105.10 Refusal to accept a premarket submission.

(a) FDA will refuse to accept for review, as soon as practicable, a premarket tobacco product application, modified risk tobacco product application, substantial equivalence application, or exemption request or subsequent abbreviated report for the following reasons, if applicable:

(1) The submission does not pertain to a tobacco product as defined in 21 U.S.C. 321(rr).

(2) The submission is not in English or does not contain complete English translations of any information submitted within.

(3) If submitted in an electronic format, the submission is in a format that FDA cannot process, read, review, and archive.

(4) The submission does not contain contact information, including the applicant's name and address.

(5) The submission is from a foreign applicant and does not identify an authorized U.S. agent, including the agent's name and address, for the submission.

(6) The submission does not contain a required FDA form(s).

(7) The submission does not contain the following product-identifying information: The manufacturer of the tobacco product; the product name, including the brand and subbrand; the product category and subcategory; package type and package quantity; and characterizing flavor.

(8) The type of submission is not specified.