(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.

(9) The submission does not contain a signature of a responsible official, authorized to represent the applicant, who either resides in or has a place of business in the United States.

(10) For premarket tobacco applications, modified risk tobacco product applications, substantial equivalence applications, and exemption requests only: The submission does not include a valid claim of categorical exclusion in accordance with part 25 of this chapter, or an environmental assessment.

(b) If FDA finds that none of the reasons in paragraph (a) of this section exists for refusing to accept a premarket submission, FDA may accept the submission for processing and further review. FDA will send to the submitter an acknowledgement letter stating the submission has been accepted for processing and further review and will provide the premarket submission tracking number.

(c) If FDA finds that any of the reasons in paragraph (a) of this section exist for refusing to accept the submission, FDA will notify the submitter in writing of the reason(s) and that the submission has not been accepted, unless insufficient contact information was provided.

PART 1107—EXEMPTION REQUESTS AND SUBSTANTIAL EQUIVALENCE REPORTS

Subpart A—Exemptions

Subpart B—General

Subpart C—Substantial Equivalence Reports

Subpart D—FDA Review

Subpart E—Miscellaneous

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

SOURCE: 76 FR 38974, July 5, 2011, unless otherwise noted.

Subpart A—Exemptions

§ 1107.1 Exemptions.

(a) *General requirements.* Under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(3)), FDA may exempt from the requirements relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j), tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that:

(1) Such modification would be a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act (a legally marketed tobacco product);

(2) A report under section 905(j)(1) intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(3) An exemption is otherwise appropriate.

(b) *Request for an exemption under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.* A request for an exemption from the requirement of demonstrating substantial equivalence may be made only by the manufacturer of a legally marketed tobacco product