(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

Sec.

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

for a minor modification to that tobacco product. To request an exemption, the manufacturer must submit the request and all information supporting the request in an electronic format that FDA can process, review, and archive. If the manufacturer is unable to submit an exemption request in an electronic format, the manufacturer may submit a written request to the Center for Tobacco Products explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative format. Such request must include an explanation of why an alternative format is necessary. All submissions, including requests to submit the information in an alternative format, requests for exemptions, and all supporting information must be legible and in the English language. An exemption request must contain:

(1) The manufacturer's address and contact information;

(2) Identification of the tobacco product(s);

(3) A detailed explanation of the purpose of the modification;

(4) A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;

(5) A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act;

(6) A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug, and Cosmetic Act 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;

(7) A certification (*i.e.*, a signed statement by a responsible official of the manufacturer) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;

(8) Other information justifying an exemption; and

(9) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

(c) *Exemption determination.* FDA will review the information submitted and determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act are met. FDA may request additional information if necessary to make a determination. FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.

(d) *Rescission of an exemption.* FDA may rescind an exemption if it finds that the exemption is not appropriate for the protection of public health. In general, FDA will rescind an exemption only after notice and opportunity for a hearing under part 16 of this chapter is provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 of this chapter if the continuance of the exemption presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

[76 FR 38974, July 5, 2011]

§ 1107.3 Recordkeeping.

(a) *Definition.* The term ''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.

(b) *Record maintenance.* (1) Each applicant who submits an abbreviated report under section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act and receives a letter acknowledging the receipt of an abbreviated report from FDA must maintain all records (including those created by third parties on the applicant's behalf) that support the submission. Such records may include, but are not limited to:

(i) A copy of the abbreviated report and, if applicable, the exemption request and all amendments thereto.

(ii) A copy of the acknowledgement letter issued in response to an abbreviated report and, if applicable, the exemption order issued by FDA.

(iii) Documents related to formulation of product, design specifications, packaging, and related items.

(iv) Documents showing design specifications are consistently met.

(v) Documents related to product packing and storage conditions.

(vi) Analytical test method records, including:

(A) Performance criteria.

(B) Validation or verification documentation; and

(C) Reports/results from these test methods.

(vii) Source data and related summaries.

(2) An applicant that submits an abbreviated report for a modification to a Pre-Existing Tobacco Product must also maintain records demonstrating that the Pre-Existing Tobacco Product was commercially marketed in the United States as of February 15, 2007, such as the records described in §1100.204 of this chapter.

(3) An applicant that submits an abbreviated report for a modification to a tobacco product that previously received premarket authorization (*i.e.*, an exemption (and for which the applicant has submitted an abbreviated report under section 905(j)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act, a substantially equivalent order under section 910(a), or a marketing granted order under section 910(c)) must maintain a copy of the exemption order, substantially equivalent order, or marketing granted order.

(4) An applicant that submits an abbreviated report for a modification to a tobacco product that is the subject of a pending SE report and is marketed pursuant to section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act must maintain all communications to and from FDA relating to the pending SE Report (*e.g.*, acknowledgement letter, deficiency letters), including the SE Report.

(c) *Record quality*. 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.

(d) *Record retention*. All records required by this subpart must be retained for a period of 4 years from the date that an acknowledgement letter is issued by FDA.

[86 FR 55412, Oct. 5, 2021]

Subpart B—General

SOURCE: 86 FR 55275, Oct. 4, 2021, unless otherwise noted.

§ 1107.10 Scope.

(a) Subparts B through E of this part apply to a substantial equivalence report (or an SE Report) for a new tobacco product, other than ''premium'' cigars as defined in §1107.12, that has:

(1) Characteristics different from a predicate tobacco product and for which information is submitted to demonstrate it is not appropriate to regulate the product under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health or

(2) The same characteristics as a predicate tobacco product.

(b) These subparts set forth procedures and requirements for the submission to FDA of an SE Report under sections 905 and 910 of the Federal, Food, Drug, and Cosmetic Act; the basic criteria for establishing substantial equivalence; and the general procedures FDA will follow when evaluating submissions.

§ 1107.12 Definitions.

For 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 product; or

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

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that the term does not include tobacco or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

Applicant means any manufacturer of tobacco products who is subject to chapter IX of the Federal Food, Drug, and Cosmetic Act that submits a premarket application to receive marketing authorization for a new tobacco product.

Brand means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name(s), identifiable pattern of colors, or any combination of such attributes.

Characteristic means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Commercial distribution means any distribution of a tobacco product, whether domestic or imported, to consumers or to any person, but does not include interplant transfers of a tobacco product between establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for personal consumption or resale. ''Commercial distribution'' does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption.

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.

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.

Composition means the materials in a tobacco product, including ingredients, additives, and biological organisms. The term includes the manner in which the materials, for example, ingredients, additives, and biological organisms, are arranged and integrated to produce a tobacco product.

Constituent means any chemical or chemical compound in a tobacco product that is or potentially is inhaled, ingested, or absorbed into the body, any chemical or chemical compound in an emission (*e.g.*, smoke, aerosol, droplets) from a tobacco product, that either transfers from any component or part of the tobacco product to the emission or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

Container closure system means any packaging materials that are a component or part of a tobacco product.

Design means the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product.

Distributor means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Finished tobacco product means a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold to consumers separately or as part of kits) or in the final form in which it is intended to be sold to consumers.

Harmful or potentially harmful constituent (HPHC) means any chemical or chemical compound in a tobacco product or tobacco smoke or emission that:

(1) Is or potentially is inhaled, ingested, or absorbed into the body, including as an aerosol or any other emission; and

(2) Causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

Health information statement means a statement, made under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, that the health information related to a new tobacco product will be made available upon request by any person.

Health information summary means a summary, submitted under section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, of any health information related to a new tobacco product.

Heating source means the source of energy used to burn or heat the tobacco product.

Ingredient means tobacco, substances, compounds, or additives contained within or added to the tobacco, paper, filter, or any other component or part of a tobacco product, including substances and compounds reasonably expected to be formed through a chemical reaction during tobacco product manufacturing.

Material means an assembly of ingredients. Materials are assembled to form a tobacco product or components or parts of tobacco products.

New tobacco product means:

(1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(2) 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.

Other features means any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. Such other features include harmful and potentially harmful constituents and any other product characteristics that relate to the chemical, biological, and physical properties of the 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.

Predicate tobacco product means a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

Premium cigars means a type of cigar that:

(1) Is wrapped in whole tobacco leaf;

(2) Contains a 100 percent leaf tobacco binder;

(3) Contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.,* whole tobacco leaves that run the length of the cigar);

(4) Is handmade or hand rolled (*i.e.,* no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling);

(5) Has no filter, nontobacco tip, or nontobacco mouthpiece;

(6) Does not have a characterizing flavor other than tobacco;

(7) Contains only tobacco, water, and vegetable gum with no other ingredients or additives; and

(8) Weighs more than 6 pounds per 1,000 units.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and voluntary requests for determinations that a tobacco product was commercially marketed in the United States as of February 15, 2007.

Substantial equivalence or *substantially equivalent* means, with respect to a new tobacco product being compared to a predicate tobacco product, that FDA by order has found that the new tobacco product:

(1) Has the same characteristics as the predicate tobacco product; or

(2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

Substantial equivalence report or *SE Report* means a submission under section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial substantial equivalence report and all subsequent amendments.

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 a 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.

[86 FR 55275, Oct. 4, 2021, as amended at 88 FR 16552, Mar. 20, 2023]

Subpart C—Substantial Equivalence Reports

SOURCE: 86 FR 55275, Oct. 4, 2021, unless otherwise noted.

§ 1107.16 Submission of a substantial equivalence report.

An applicant may submit an SE Report intended to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product. The applicant must submit the SE Report at least 90 calendar days prior to the date the applicant intends to introduce or deliver for introduction a new tobacco product into interstate commerce for commercial distribution. The applicant cannot begin commercial distribution of the new tobacco product until FDA has provided the applicant an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product, unless the new tobacco product has received authorization to be marketed through another premarket pathway.

§ 1107.18 Required content and format of an SE Report.

(a) *Overview.* The SE Report must provide information uniquely identifying the new tobacco product and the predicate tobacco product, and compare the new tobacco product to either a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent. The SE Report must provide sufficient information as described in this section to enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007. If FDA cites deficiencies and requests information to support a statement in the SE Report, the applicant must provide that information for review to continue, or FDA may issue an order under § 1107.48. FDA generally intends to refuse to accept an SE Report for review if it does not comply with

§ 1105.10 and this section. The SE Report must contain the following information:

(1) General information (as described in paragraph (c) of this section);

(2) Summary (as described in paragraph (d) of this section);

(3) New tobacco product description (as described in paragraph (e) of this section);

(4) Predicate tobacco product description (as described in paragraph (f) of this section), including a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the submission tracking number of the SE order finding the predicate product SE, or the submission tracking number of, or information to support, that the predicate tobacco product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007;

(5) Comparison information (as described in paragraph (g) of this section);

(6) Comparative testing information (as described in paragraph (h) of this section);

(7) Statement of compliance with applicable tobacco product standards (as described in paragraph (i) of this section);

(8) Health information summary or statement that such information will be made available upon request (as described in paragraph (j) of this section);

(9) Compliance with part 25 of this chapter (as described in paragraph (k) of this section); and

(10) Certification statement (as described in paragraph (*l*) of this section).

(b) *Format.* The applicant must submit the SE Report using the form(s) that FDA provides. The SE Report must contain a comprehensive index and table of contents, be well-organized and legible, and be written in English. As described in § 1107.62, the applicant must submit the SE Report and all information supporting the SE Report in an electronic format that FDA can process, read, review, and archive, unless FDA has provided a waiver under § 1107.62(b).

(c) *General information.* The SE Report must include the following information, using the form FDA provides:

(1) The date the SE Report is submitted;

(2) Type of submission (*e.g.*, the SE Report or amendment to a report);

(3) FDA STN, if previously assigned;

(4) Any other relevant FDA STN, such as a voluntary request for a determination that a tobacco product was commercially marketed in the United States as of February 15, 2007, or SE Report previously found substantially equivalent (if applicable), and cross-references to meetings with FDA regarding the new tobacco product;

(5) Applicant name, address, and contact information (including email address);

(6) Authorized representative or U.S. agent (for a foreign applicant), including the name, address, and contact information (including email address);

(7) For both the new and predicate tobacco products, the following information to uniquely identify the products:

(i) Manufacturer;

(ii) Product name, including the brand and sub brand (or other commercial name used in commercial distribution); and

(iii) Product category, product subcategory, and product properties (if the product does not have a listed product property, *e.g.*, ventilation or characterizing flavor, the report must state ''none'' for that property) as provided in the following table:

TABLE 1 TO § 1107.18(c)(7)(iii)

Tobacco product category	Tobacco product subcategory	Product properties
(A) Cigarettes	(*1*) Filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 millimeters (mm), 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*2*) Non-filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Other	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(B) Roll-Your-Own Tobacco Products.	(*1*) Roll-Your-Own Tobacco Filler.	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20.1 grams (g), 16 ounces (oz.)). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Rolling Paper	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 50 sheets, 200 papers). —Length (*e.g.,* 79.1 mm, 100 mm, 110.2 mm). —Width (*e.g.,* 28.1 mm, 33 mm, 45.2 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Filtered Cigarette Tube	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Non-Filtered Cigarette Tube.	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Filter	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 filters, 200 filters). —Length (*e.g.,* 8 mm, 12.1 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Paper Tip	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 200 tips, 275 tips). —Length (*e.g.,* 12 mm, 15.1 mm). —Width (*e.g.,* 27.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Other	—Package type (*e.g.,* bag, box, booklet). —Product quantity (*e.g.,* 200 tips, 100 filters, 200 tubes). —Characterizing flavor(s) (*e.g.,* none, menthol, tobacco). —Additional properties needed to uniquely identify the tobacco product.
(C) Smokeless Tobacco Products.	(*1*) Loose Moist Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable, *e.g.,* fine cut, long cut, straight cut).
	(*2*) Portioned Moist Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 1 g/piece). —Portion length (*e.g.,* 15 mm, 20.1 mm). —Portion width (*e.g.,* 10 mm, 15.1 mm). —Portion thickness (*e.g.,* 5 mm, 7.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Loose Snus	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Portioned Snus	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 1 g/piece). —Portion length (*e.g.,* 15 mm, 20.1 mm). —Portion width (*e.g.,* 10 mm, 15.1 mm). —Portion thickness (*e.g.,* 5 mm, 7.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Loose Dry Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Dissolvable	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 sticks, 20 pieces). —Portion mass (*e.g.,* 1.5 g/strip, 1 g/piece). —Portion length (*e.g.,* 10 mm, 15.1 mm). —Portion width (*e.g.,* 5 mm, 8.1 mm). —Portion thickness (*e.g.,* 3 mm, 4.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Loose Chewing Tobacco	—Package type (*e.g.,* bag, pouch, wrapped). —Product quantity (*e.g.,* 20 g, 3.1 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*8*) Portioned Chewing Tobacco.	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 10 bits). —Portion mass (*e.g.,* 2.1 g/bit). —Portion length (*e.g.,* 8 mm, 10.1 mm). —Portion width (*e.g.,* 6 mm, 8.1 mm). —Portion thickness (*e.g.,* 5.1 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*9*) Other	—Package type (*e.g.,* box, bag, can). —Product quantity (*e.g.,* 20.1 g, 22.5 g, 3 oz.). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco). —Additional properties needed to uniquely identify the tobacco product.

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
(D) Electronic Nicotine Delivery Systems (ENDS) (Vapes).	(*1*) Open E-Liquid	—Package type (*e.g.,* bottle, box, pod). —Product quantity (*e.g.,* 1 bottle, 5 bottles). —E-liquid volume (*e.g.,* 0.5 milliliters (ml)), 2 ml, 5.1 ml). —Nicotine concentration (*e.g.,* 0 mg/ml), 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle). —Propylene Glycol (PG)/Vegetable Glycerin (VG) ratio (*e.g.,* not applicable (N/A), 0/100, 50/50, 100/0). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Closed E-Liquid	—Package type (*e.g.,* cartridge, pod). —Product quantity (*e.g.,* 1 cartridge, 5 cartridges). —E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml). —Nicotine concentration (*e.g.,* 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/bottle). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50, 100/0). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Closed E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Length (*e.g.,* 100 mm, 120 mm) —Diameter (*e.g.,* 6 mm, 8 mm). —Wattage (*e.g.,* 100 watts (W), 200 W). —Battery capacity (*e.g.,* 100 milliampere hours (mAh), 200 mAh). —E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml). —Nicotine concentration (*e.g.,* 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 0.2 mg/e-cigarette). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50, 100/0). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Open E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Length (*e.g.,* 100 mm, 120 mm) —Diameter (*e.g.,* 6 mm, 8 mm). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —E-liquid volume (*e.g.,* 0.5 ml, 2 ml, 5.1 ml). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) ENDS Component	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 coil). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Other	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 bottles). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen, tobacco). —Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	(*1*) Filtered, Sheet-Wrapped	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 filtered cigars, 25 filtered cigars). —Length (*e.g.,* 89.1 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 0%, 10%, 25%). —Characterizing flavor (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Unfiltered, Sheet-Wrapped	—Package type (*e.g.,* box, film sleeve). —Product quantity (*e.g.,* 1 cigar, 5 cigarillos). —Length (*e.g.,* 100.1 mm, 140 mm). —Diameter (*e.g.,* 8 mm, 10.1 mm).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*3*) Unfiltered, Leaf-Wrapped ..	—Tip (*e.g.,* none, wood tips, plastic tips). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable). —Package type (*e.g.,* box, film, sleeve, none). —Product quantity (*e.g.,* 1 cigar, 5 cigars). —Length (*e.g.,* 150.1 mm, 200 mm). h;Diameter (*e.g.,* 8 mm, 10.1 mm). —Wrapper material (*e.g.,* burley tobacco leaf, Connecticut shade grown tobacco leaf). —Characterizing flavor (*e.g.,* none, whiskey). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Cigar Component	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 10 wrappers, 20 leaves). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Cigar Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Characterizing flavor (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Other	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 1 cigar, 5 cigars, 20 leaves, 16 g). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product.
(F) Pipe Tobacco Products	(*1*) Pipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 pipe). —Length (*e.g.,* 200 mm, 300.1 mm). —Diameter (*e.g.,* 25.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Pipe Tobacco Filler	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Tobacco cut style (*e.g.,* standard cut, such as shag cut, bugler cut, loose cut, etc., or a pressed cut, such as flake, cube cut, roll cake, etc. or a mixture). —Characterizing flavor(s) (*e.g.,* none, menthol, cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Pipe Component	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Other	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 pipe, 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product.
(G) Waterpipe Tobacco Products.	(*1*) Waterpipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 waterpipe). —Height (*e.g.,* 200 mm, 500.1 mm). —Width (*e.g.,* 100.1 mm, 300 mm). —Diameter (*e.g.,* 100.1 mm, 300 mm). —No. of hoses (*e.g.,* 1, 2, 4). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Waterpipe Tobacco Filler ..	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16.1 oz.). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Waterpipe Heat Source	—Package type (*e.g.,* box, film sleeve, bag, none).

TABLE 1 TO § 1107.18(c)(7)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Product quantity (*e.g.,* 150 g, 680 g). —Portion count (*e.g.,* 20 fingers, 10 discs, 1 base). —Portion mass (*e.g.,* 15 g/finger, 10 g/brick). —Portion length (*e.g.,* 40 mm, 100 mm). —Portion width (*e.g.,* 10 mm, 40 mm). —Portion thickness (*e.g.,* 10 mm, 40 mm). —Source of energy (*e.g.,* charcoal, battery, electrical). —Characterizing flavor(s) (*e.g.,* none, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Waterpipe Component	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Other	—Package type (*e.g.,* box, bag, none). —Product quantity (*e.g.,* 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (*e.g.,* none, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
(H) Heated Tobacco Products (HTP).	(*1*) Closed HTP	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 device, 1 HTP). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Open HTP	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 device, 1 HTP). —Length (*e.g.,* 100 mm, 120 mm) —Diameter (*e.g.,* 6 mm, 8.1 mm). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Characterizing flavor(s) (*e.g.,* none). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) HTP Consumable	—Package type (*e.g.,* hard pack, soft pack, plastic clamshell). —Product quantity (*e.g.,* 20 sticks, 25 cartridges). —Length (*e.g.,* 60 mm, 82 mm.) —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) HTP Component	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 mouthpiece, 1 spacer). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Other	—Package type (*e.g.,* box, bag, plastic clamshell, none). —Product quantity (*e.g.,* 1 base, 5 capsules). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other	Other	—Package type (*e.g.,* box, bag, plastic clamshell, none). —Product quantity (*e.g.,* 1 base, 5 capsules). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(8) Address and the FDA Establishment Identifier number(s) of the establishments involved in the manufacture

and/or importation of the new and predicate tobacco products.

(d) *Summary*. The SE Report must include a summary at the beginning of the SE Report that includes the following:

(1) A concise description of the characteristics of the new tobacco product;

(2) A statement as to whether the applicant believes the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics but any differences in characteristics do not cause the new tobacco product to raise different questions of public health; and

(3) A concise description of the similarities and differences between the new tobacco product and the predicate tobacco product with respect to their characteristics (materials, ingredients, design, composition, heating source, or other features).

(e) *New tobacco product description*. The applicant must identify one new tobacco product in the SE Report for comparison to one predicate tobacco product. The SE Report must describe the new tobacco product in sufficient detail to enable FDA to evaluate its characteristics. This part of the SE Report must include:

(1) A narrative description of the new tobacco product and detailed drawings or schematics of the new tobacco product, including its container closure system, illustrating all components or parts of the product. For a portioned tobacco product, the SE Report must also include a diagram illustrating all components or parts of the individual unit of use;

(2) A description and the function of each component or part of the new tobacco product, and an explanation of how each component or part is integrated into the design of the new tobacco product; and

(3) A concise overview of the process used to manufacture the new tobacco product. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision.

(f) *Description of predicate tobacco product*. (1) The applicant must identify a predicate tobacco product that is either a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007, or a tobacco product that FDA previously found to be substantially equivalent.

(2) A tobacco product to which a new tobacco product is compared must:

(i) Have been either:

(A) Commercially marketed (other than for test marketing) in the United States as of February 15, 2007, as shown by either specific information sufficient to support this in the SE Report, including a statement that ''I, (insert name and position title of responsible official), confirm that the predicate tobacco product associated with this submission, (insert name of predicate tobacco product), was commercially marketed (other than for test marketing) in the United States as of February 15, 2007,'' and, if applicable, reference to an STN for a previous determination by FDA that the predicate product was commercially marketed (other than for test marketing) in the United States as of February 15, 2007; or

(B) Previously determined to be substantially equivalent by FDA;

(ii) Be an individual product and not a composite of multiple products;

(iii) Not be the subject of a rescission action by FDA, as described in §1107.50; and

(iv) Not have been removed from the market at the initiative of FDA and not have been determined by judicial order to be adulterated or misbranded.

(g) *Comparison information*. The SE Report must include a comparison of the characteristics of the new tobacco product and the predicate tobacco product. If the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (*e.g.*, a change to product quantity), the applicant must provide comparison information related to any characteristic(s) that have changed, but may certify that the other characteristics are identical under paragraph (l)(2) of this section. The applicant must maintain records supporting the certification consistent with §1107.58.

(h) *Comparative testing information*. Other than for characteristics that are

identical, and for which the applicant has certified that the characteristics are identical under paragraph (l)(2) of this section, the SE Report must provide comparative testing information that has been demonstrated to be fully validated on the characteristics of the new and predicate tobacco products except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product:

(1) Has the same characteristics as the predicate or

(2) Does not raise different questions of public health.

(i) *Statement of compliance with applicable tobacco product standards.* The SE Report must either:

(1) List and describe the action(s) taken by the applicant to comply with applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act; or

(2) State there are no applicable requirements under section 907 of the Federal Food, Drug, and Cosmetic Act.

(j) *Health information summary or statement regarding availability of such information.* The SE Report must include either a health information summary or a statement that such information will be made available upon request, as provided in section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, in accordance with the following:

(1) *Health information summary.* If including a health information summary with the SE Report, the applicant must provide a copy of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter; and either

(i) Provide accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product that is not contained in the SE Report; or

(ii) Provide the following statement, if true, about the new tobacco product: ''Applicant does not have or know of any additional health information, including information, research or data regarding adverse health effects, about the new tobacco product that is the subject of this SE Report.''

(2) *Statement regarding availability of health information.* If the applicant chooses to make the health information available upon request, the SE Report must include the following statement, with the appropriate applicant information inserted as indicated by parenthetical text, signed by an authorized representative of the applicant, made on a separate page of the SE Report, and clearly identified as ''910(a)(4) health information statement'': ''I certify that, in my capacity as (*the position held in company by person required to submit the SE Report, preferably the responsible official of the applicant*) of (*company name*), I will make available, upon request, the information identified in 21 CFR 1107.18(j)(3) within 30 calendar days of a request.''

(3) *Content of health information.* The health information the applicant agrees to make available in paragraph (j)(2) of this section must be a copy of the full SE Report, excluding all research subject identifiers, trade secrets, and confidential commercial information, as defined in §§ 20.61 and 20.63 of this chapter; and either:

(i) Accurate, complete, and not false or misleading, additional health information, including information, research, or data about adverse health effects, that the applicant has or knows about concerning the new tobacco product and that is not contained in the SE Report; or

(ii) The following statement, if true, about the new tobacco product: ''(*Company name*) does not have or know of any additional health information, including information, research or data regarding adverse health effects about the new tobacco product that is the subject of the provided SE Report.''

(4) *Requests for information.* All requests for information under paragraph (j)(2) of this section must be made in writing to the authorized representative of the applicant, whose contact information will be posted on the FDA website listing substantial equivalence determinations. The applicant must provide FDA any updated information if the contact information changes.

(5) *No modified risk violations.* To the extent information is included in the health information summary or health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or this paragraph (j), that information must not contain a statement that would cause the tobacco product to be in violation of section 911 of the Federal Food, Drug, and Cosmetic Act upon the introduction or delivery for introduction of the proposed new product into interstate commerce.

(k) *Compliance with part 25 of this chapter.* (1) The SE Report must include an environmental assessment prepared in accordance with §25.40 of this chapter, or a valid claim of categorical exclusion. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under §25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under §25.21.

(2) The environmental assessment must include a statement explaining whether the new tobacco product is intended to replace the predicate tobacco product after the new tobacco product receives market authorization, is intended to be a line extension of the predicate tobacco product, is intended to be introduced as an additional product by the same manufacturer, or if the new tobacco product will be introduced as an additional product but by a different manufacturer.

(l) *Certification statement.* (1) The SE Report must contain the following certification, with the appropriate information inserted (as indicated by parenthetical text), and be signed by an authorized representative of the applicant: ''I (*name of responsible official*) on behalf of (*applicant*), hereby certify that (*applicant*) will maintain all records to substantiate the accuracy of this SE Report for the period of time required in 21 CFR 1107.58 and ensure that such records remain readily available to the FDA upon request. I certify that this information and the accompanying submission are true and correct, that no material fact has been omitted, and that I am authorized to submit this on the applicant's behalf. I understand that under section 1001 of title 18 of the United States Code anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States is subject to criminal penalties.''

(2) The SE Report must include the following certification, as well as a justification for the certification, if an applicant chooses to certify that certain characteristics are identical in lieu of providing data for each characteristic of the new and predicate tobacco products. This certification must include the appropriate information inserted (as indicated by parenthetical text) and be signed by an authorized representative of the applicant: ''I, (*name of responsible official*), on behalf of (*name of company*), certify that (*new tobacco product name*) has the following modification(s) as compared to (*name of predicate tobacco product*): (*describe modification(s), e.g., change in product quantity or change in container closure system*). Aside from these modifications, the characteristics of (new tobacco product name) and (name of predicate tobacco product) are identical. I certify that (*name of company*) understands this means there is no other modification to the materials, ingredients, design features, heating source, or any other feature. I also certify that (*name of company*) will maintain records to support the comparison information in 21 CFR 1107.19 that substantiate the accuracy of this statement for the period of time required in 21 CFR 1107.58, and ensure that such records remain readily available to FDA upon request.''

§ 1107.19 Comparison information.

The SE Report must include a comparison of the characteristics of the new tobacco product to the predicate tobacco product. Where test data is submitted, the testing information must include the test protocols, quantitative acceptance criteria, and test

results (including means and variances, data sets, and a summary of the results). Comparison testing must be conducted on a sufficient sample size and on test samples that reflect the finished tobacco product composition and design. The SE report must state whether the same test methods were used for the new tobacco product and the predicate product, and if the methods differed, an explanation as to how the results of the different test methods can be compared. The SE report must identify national and international standards used to test the new and predicate tobacco products and explain any deviations from the standard, or state that no standards were used for the testing. The SE report must include the following:

(a) *Comparison of product design*. The SE Report must include a description of the product designs of the new and predicate tobacco products and an identification of any differences. The SE Report must include, in a tabular format, a side-by-side comparison of each design parameter of the new and predicate tobacco products. The target specification and upper and lower range limits must be provided for each design parameter. Test data (including test protocols, quantitative acceptance criteria, data sets (*i.e.*, measured values), and a summary of the results) must be provided for the new and predicate tobacco products when the target specification or range limits of the new tobacco product differ from the predicate tobacco product. For tobacco cut size or particle size, when target specifications and range limits are not available, the following alternative information may be submitted in place of this information: A description of the tobacco cutting process (including a complete description of the milling, cutting, and sifting process; the control parameters of the miller or cutter; and any sift specifications) or the measured particle size distribution for the new and predicate tobacco products.

(1) *Cigarettes*. For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 1 TO § 1107.19(a)(1)

Provide Target Specification With Upper and Lower Range Limits for:
—Cigarette length (mm).
—Cigarette circumference or diameter (mm).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (mm or cuts per inch (CPI)).
—Filter ventilation (%).
—Tipping paper length (mm).
—Cigarette paper base paper porosity (CORESTA unit (CU)) or permeability.
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm).
—Cigarette paper band space (mm).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))).
—Filter length (mm).
—Filter pressure drop (mm H_2O).

TABLE 2 TO § 1107.19(a)(1)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco filler mass (mg).
—Tobacco moisture (%) or oven volatiles (%).
—Filter ventilation (%).

TABLE 2 TO § 1107.19(a)(1)—Continued

—Tobacco cut size (mm or CPI).
—Cigarette paper base paper porosity (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Filter pressure drop (mm H_2O).

(2) *Smokeless Tobacco.* For portioned and non-portioned smokeless tobacco products, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 3 TO § 1107.19(a)(2)

Provide Target Specification With Upper and Lower Range Limits for:
Portioned Smokeless Tobacco Products:
—Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
—Tobacco moisture (%).
—Portion length (mm).
—Portion width (mm).
—Portion mass (mg).
—Pouch material thickness (mm) (if applicable).
—Pouch material porosity or permeability (CU or $L/m^2/s$) (if applicable).
—Pouch material basis weight (g/m^2). (if applicable).
—Nicotine dissolution rate (%/min) (if applicable).
Non-portioned Smokeless Tobacco Products:
—Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
—Tobacco moisture (%).

TABLE 4 TO § 1107.19(a)(2)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
Portioned Smokeless Tobacco Products:
—Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
—Tobacco moisture (%).
—Portion mass (mg).
—Pouch material porosity or permeability (CU or $L/m^2/s$).
—Pouch material basis weight (g/m^2).
—Nicotine dissolution rate (%/min) (if applicable).
Non-portioned Smokeless Tobacco Products:
—Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron).
—Tobacco moisture (%).

(3) *Roll-your-own tobacco, rolling papers.* For roll-your-own tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 5 TO § 1107.19(a)(3)

Provide Target Specifications With Upper and Lower Range Limits for:
—Paper length (mm).

TABLE 5 TO § 1107.19(a)(3)—Continued

—Paper width (mm).
—Mass per paper (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm) (if applicable).
—Cigarette paper band space (mm) (if applicable).

TABLE 6 TO § 1107.19(a)(3)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Mass per paper (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity or permeability (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).

(4) *Roll-your-own tobacco, non-filtered tubes.* For roll-your-own tobacco non-filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 7 TO § 1107.19(a)(4)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tube length (mm).
—Tube circumference or diameter (mm).
—Tube mass (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigarette paper band width (mm) (if applicable).
—Cigarette paper band space (mm) (if applicable).

TABLE 8 TO § 1107.19(a)(4)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tube mass (mg).
—Cigarette paper base paper basis weight (g/m^2).
—Cigarette paper base paper porosity (CU).
—Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)).

(5) *Roll-your-own tobacco, filtered tubes.* For roll-your-own tobacco filtered tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 9 TO § 1107.19(a)(5)

Provide Target Specifications With Upper and Lower Range Limits for: —Tube length (mm). —Tube circumference or diameter (mm). —Tube mass (mg). —Tipping paper length (mm). —Filter ventilation (%). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity or permeability (CU). —Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable). —Cigarette paper band width (mm) (if applicable). —Cigarette paper band space (mm) (if applicable). —Filter length (mm). —Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))). —Filter pressure drop (mm H_2O).

TABLE 10 TO § 1107.19(a)(5)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters: —Tube mass (mg). —Filter ventilation (%). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity or permeability (CU). —Cigarette paper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable). —Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))). —Filter pressure drop (mm H_2O).

(6) *Roll-your-own tobacco.* For roll-your-own tobacco, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 11 TO § 1107.19(a)(6)

Provide Target Specifications With Upper and Lower Range Limits for: —Tobacco cut size (mm or CPI). —Tobacco moisture (%) or oven volatiles (%).

TABLE 12 TO § 1107.19(a)(6)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters: —Tobacco cut size (mm or CPI). —Tobacco moisture (%) or oven volatiles (%).

(7) *Filtered, sheet-wrapped cigars.* For filtered, sheet-wrapped cigars, the required design parameter information to

be provided for each predicate and new tobacco product is as follows:

TABLE 13 TO § 1107.19(a)(7)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar mass (mg).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder length (mm).
—Cigar binder width (mm).
—Cigar binder basis weight (g/m^2).
—Cigar length (mm).
—Cigar overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper porosity or permeability (CU).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar wrapper band width (mm) (if applicable).
—Cigar wrapper band space (mm) (if applicable).
—Tipping paper length (mm).
—Cigar binder porosity or permeability (CU).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigar filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).
—Filter diameter (mm).
—Filter ventilation (%).

TABLE 14 TO § 1107.19(a)(7)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Cigar mass (mg).
—Puff count.
—Cigar wrapper basis weight (g/m^2).
—Cigar wrapper porosity or permeability (CU).
—Cigar binder porosity or permeability (CU).
—Cigar binder basis weight (g/m^2).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Tobacco moisture or oven volatiles (%).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).

TABLE 14 TO § 1107.19(a)(7)—Continued

—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Filter ventilation (%).
—Filter pressure drop (mm H_2O).

(8) *Unfiltered, sheet-wrapped cigars.* For unfiltered, sheet-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 15 TO § 1107.19(a)(8)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar length (mm).
—Cigar mass (mg).
—Cigar overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper porosity or permeability (CU).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder porosity or permeability (CU).
—Cigar binder width (mm) (if applicable).
—Cigar binder basis weight (g/m^2).
—Cigar tip mass (mg) (if applicable).
—Tip length (mm) (if applicable).
—Tip inner diameter (mm) (if applicable).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band width (mm) (if applicable).
—Cigar binder band space (mm) (if applicable).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar wrapper band width (mm) (if applicable).
—Cigar wrapper band space (mm) (if applicable).

TABLE 16 TO § 1107.19(a)(8)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Puff count.
—Cigar mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Tobacco moisture or oven volatiles (%).
—Tobacco filler mass (mg).
—Cigar wrapper basis weight (g/m^2).

TABLE 16 TO § 1107.19(a)(8)—Continued

—Cigar wrapper porosity or permeability (CU).
—Cigar binder width (mm) (if applicable).
—Cigar binder basis weight (g/m^2).
—Cigar binder porosity or permeability (CU).
—Cigar wrapper band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar binder band porosity or permeability (CU) (alternately, band diffusivity (cm^2/s)) (if applicable).
—Cigar tip mass (mg) (if applicable).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).

(9) *Unfiltered, leaf-wrapped cigars.* For unfiltered, leaf-wrapped cigars, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 17 TO § 1107.19(a)(9)

Provide Target Specifications With Upper and Lower Range Limits for:
—Cigar length (mm).
—Cigar mass (mg).
—Overall diameter (mm).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).
—Cigar wrapper length (mm).
—Cigar wrapper width (mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder width (mm).
—Cigar binder basis weight (g/m^2).

TABLE 18 TO § 1107.19(a)(9)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Puff count.
—Cigar mass (mg).
—Tobacco filler mass (mg).
—Tobacco rod density (g/cm^3).
—Tobacco cut size (CPI or mm).
—Cigar wrapper basis weight (g/m^2).
—Cigar binder basis weight (g/m^2).
—Tobacco moisture or oven volatiles (%).
—Cigar minimum diameter (mm) (if applicable).
—Cigar maximum diameter (mm) (if applicable).

(10) *Cigar filler.* For cigar filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 19 TO § 1107.19(a)(10)

Provide Target Specifications With Upper and Lower Range Limits for: —Tobacco moisture or oven volatiles (%). —Tobacco cut size (CPI or mm).

TABLE 20 TO § 1107.19(a)(10)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters: —Tobacco moisture or oven volatiles (%). —Tobacco cut size (CPI or mm).

(11) *Cigar component.* For cigar components, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 21 TO § 1107.19(a)(11)

Provide Target Specifications With Upper and Lower Range Limits for: —Cigar wrapper length (mm). —Cigar wrapper width (mm). —Cigar wrapper porosity (CU). —Cigar wrapper basis weight (g/m^2).

TABLE 22 TO § 1107.19(a)(11)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters: —Cigar wrapper length (mm). —Cigar wrapper width (mm). —Cigar wrapper basis weight (g/m^2).

(12) *Pipes.* For pipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 23 TO § 1107.19(a)(12)

Provide Target Specifications With Upper and Lower Range Limits for: —Bowl chamber outer diameter (mm). —Bowl chamber inner diameter (mm). —Draught hole diameter (mm). —Draught hole location. —Draught hole shape. —Bowl chamber hole shape. —Bowl chamber volume (cm^3). —Stem length (mm). —Stem diameter (mm). —Shank length (mm). —Shank diameter (mm). —Draught hole area (mm^2). —Pressure drop through air valve (mm H_2O). —Air flow through air valve (cc/min).

TABLE 23 TO § 1107.19(a)(12)—Continued

—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).

TABLE 24 TO § 1107.19(a)(12)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Bowl chamber volume (cm^3).
—Air flow through air valve (cc/min).
—Filter length (mm).
—Filter pressure drop (mm H_2O).
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density (g/cm^3))).

(13) *Pipe filler*. For pipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 25 TO § 1107.19(a)(13)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

TABLE 26 TO § 1107.19(a)(13)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

(14) *Waterpipes*. For waterpipes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 27 TO § 1107.19(a)(14)

Provide Target Specifications With Upper and Lower Range Limits for:
—Hose length (mm).
—Hose internal diameter (mm).
—Hose materials.
—Stem length (mm).
—Stem internal diameter (mm).
—Base diameter (mm).
—Base volume (cm^3).
—Base shape.
—Pressure drop (mm H_2O).
—Water filter efficiency (%).
—Hose air permeability (CU).
—Head height (mm).
—Head top diameter (mm).

TABLE 27 TO § 1107.19(a)(14)—Continued

—Head bottom diameter (mm).
—No. of holes.
—Head volume (mm^3).
—Heating source type.
—Head materials.

TABLE 28 TO § 1107.19(a)(14)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Hose length (mm).
—Hose internal diameter (mm).
—Stem length (mm).
—Stem internal diameter (mm).
—Base diameter (mm).
—Base volume (cm^3).
—Pressure drop (mm H_2O).
—Water filter efficiency (%).
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—Head volume (mm^3).

(15) *Waterpipe, heating source.* For waterpipe heating sources, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 29 TO § 1107.19(a)(15)

Provide Target Specifications With Upper and Lower Range Limits for:
—Heating element mass (mg).
—Heating element density (g/cm^3).
—Heating element resistance (ohms) (if applicable).
—No. of heating elements.
—Heating element configuration.
—Heating element diameter (gauge).
—Battery current rating (mA) (if applicable).
—Battery capacity (mAh) (if applicable).
—Battery voltage operating range (volts) (if applicable).
—Battery current operating range (amps) (if applicable).
—Power delivery unit (PDU) voltage operating range (volts) (if applicable).
—PDU current operating range (amps) (if applicable).
—PDU wattage operating range (watts) (if applicable).
—PDU temperature cut-off (°C) (if applicable).

TABLE 30 TO § 1107.19(a)(15)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Heating element temperature range (°C) (if applicable).
—Heating element mass (mg).
—Heating element density (g/cm^3).
—Heating element resistance (ohms) (if applicable).
—Heating element diameter (gauge).

TABLE 30 TO § 1107.19(a)(15)—Continued

—Battery current rating (mA) (if applicable).
—Battery capacity (mAh) (if applicable).
—Battery voltage operating range (volts) (if applicable).
—Battery current operating range (amps) (if applicable).
—Power delivery unit (PDU) voltage operating range (volts) (if applicable).
—PDU current operating range (amps) (if applicable).
—PDU wattage operating range (watts) (if applicable).
—PDU temperature cut-off (°C) (if applicable).

(16) *Waterpipe component, head.* For waterpipe heads, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 31 TO § 1107.19(a)(16)

Provide Target Specifications With Upper and Lower Range Limits for:
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—No. of holes.
—Head volume (mm^3).
—Head materials.

TABLE 32 TO § 1107.19(a)(16)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Head height (mm).
—Head top diameter (mm).
—Head bottom diameter (mm).
—Head volume (mm^3).

(17) *Waterpipe component, foil.* For waterpipe foil, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 33 TO § 1107.19(a)(17)

Provide Target Specifications With Upper and Lower Range Limits for:
—Length (mm) (for square or rectangular shape foil).
—Width (mm) (for square or rectangular shape foil).
—Diameter (mm) (for circular shape foil).
—Foil thickness (mm).
—No. of holes.
—Diameter of the holes (mm).

TABLE 34 TO § 1107.19(a)(17)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Length (mm) (for square or rectangular shape foil).
—Width (mm) (for square or rectangular shape foil).
—Diameter (mm) (for circular shape foil).

TABLE 34 TO § 1107.19(a)(17)—Continued

—Foil thickness (mm).
—Diameter of the holes (mm).

(18) *Waterpipe filler*. For waterpipe filler, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 35 TO § 1107.19(a)(18)

Provide Target Specifications With Upper and Lower Range Limits for:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

TABLE 36 TO § 1107.19(a)(18)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Tobacco moisture or oven volatiles (%).
—Tobacco cut size (CPI or mm).

(19) *Electronic Nicotine Delivery System (ENDS)*. For ENDS (vapes), the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 37 TO § 1107.19(a)(19)

Provide Target Specifications With Upper and Lower Range Limits for:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge).
—Atomizer tank/cartridge volume (mL).
—No. of heating elements (*e.g.,* coil).
—Heating element diameter (gauge).
—Heating element length (mm).
—Heating element resistance (Ohms).
—Heating element temperature range (°C).
—Heating element configuration (target only).
—Battery voltage operating range (V).
—Battery current operating range (mA).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery end of discharge voltage (V).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Power Delivery Unit (PDU) voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU temperature cut-off (°C) (if applicable).
—PDU current cut-off (mA) (if applicable).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).

TABLE 37 TO § 1107.19(a)(19)—Continued

—Inhaled aerosol temperature (°C).

TABLE 38 TO § 1107.19(a)(19)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge).
—Atomizer tank/cartridge volume (mL).
—Heating element diameter (gauge).
—Heating element resistance (Ohms).
—Heating element temperature range (°C).
—Battery voltage operating range (V).
—Battery current operating range (mA).
—PDU voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU current cut-off (mA) (if applicable).
—Inhaled aerosol temperature (°C).
—PDU temperature cut-off (°C) (if applicable).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Heating element length (mm).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).
—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).

(20) *E-liquids.* For e-liquids, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 39 TO § 1107.19(a)(20)

Provide Target Specifications With Upper and Lower Range Limits for:
—E-liquid viscosity (at 20 °C).
—E-liquid volume (ml).
—Particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).

TABLE 40 TO § 1107.19(a)(20)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—E-liquid viscosity (at 20 °C).
—E-liquid volume (ml).
—Particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).

(21) *Heated Tobacco Products (HTP).* For HTPs, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 41 TO § 1107.19(a)(21)

Provide Target Specifications With Upper and Lower Range Limits for:
- —Overall Device:
  - —Mass (mg).
  - —Length (mm).
  - —Width (mm).
  - —Height (mm).
  - —Diameter (mm).
  - —Draw resistance (mm H_2O).
  - —Puff count (for full tank/cartridge).
  - —Puff volume (mL).
  - —Product volume (mL).
  - —Airflow rate (L/min) (if applicable).
  - —Ventilation (%).
  - —Operational temperature (°C).
  - —Temperature sensor (if applicable).
  - —Material wrapper length (mm) (if applicable).
  - —Material wrapper width (mm) (if applicable).
  - —Material wrapper basis weight (g/m^2) (if applicable).
  - —Material porosity or permeability (CU) (if applicable).
- —Heating element:
  - —Heating element source/type/approach (electrical, carbon, aerosol, etc.).
  - —Heating element temperature range (°C).
  - —Heating element operational temperature (°C).
  - —Heating element maximum temperature (boost temperature) (°C).
  - —Heating element material.
  - —Heating element configuration.
  - —Heating element length (mm).
  - —Heating element mass (mg).
  - —Heating element location.
  - —No. of heating elements (*e.g.,* coil).
  - —Heating element diameter (gauge) (if applicable).
  - —Heating element resistance (Ohms) (if applicable).
- —Tobacco/E-liquid:
  - —Tobacco mass (mg) (if applicable).
  - —Tobacco density (g/cm^3) (if applicable).
  - —Tobacco moisture or oven volatiles (%) (if applicable).
  - —Tobacco cut size (CPI or mm) (if applicable).
  - —E-liquid volume (mL) (if applicable).
  - —E-liquid viscosity (at 20 °C) (if applicable).
- —Battery (if applicable):
  - —Battery capacity (mAh).
  - —Battery voltage operating range (V) or wattage (W).
  - —Battery current charging range (amps).
  - —Battery nominal voltage (V).
  - —Battery current rating (mA).
  - —Battery charging temperature limits (°C).
  - —Battery discharge temperature limits (°C).
  - —Battery end of discharge voltage (V).
  - —Battery maximum charging current (mA).
  - —Battery maximum discharging current (mA).
  - —Battery upper limits charging voltage (V).
  - —Power Delivery Unit (PDU) voltage operating range (V).
  - —PDU current operating range (mA).

TABLE 41 TO § 1107.19(a)(21)—Continued

—PDU wattage operating range (watts).
—PDU temperature cut-off (°C) (if applicable).
—PDU current cut-off (mA) (if applicable).
—Aerosol:
—Inhaled aerosol temperature (°C).
—Aerosol particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (μg/m^3).
—Filter (if applicable):
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter pressure drop (mm H_2O).
—Filter length (mm).
—Filter diameter (mm).
—Filter ventilation (%).

TABLE 42 TO § 1107.19(a)(21)

Where Test Data Are Necessary, As Explained in Paragraph (a) of This Section, Provide This Information for the Following Parameters:
—Overall device:
—Draw resistance (mm H_2O).
—Puff count (for full tank/cartridge) (dimensionless).
—Product volume (mL).
—Airflow rate (L/min) (if applicable).
—Ventilation (%).
—Operational temperature (°C).
—Temperature sensor (if applicable).
—Material wrapper length (mm) (if applicable).
—Material wrapper width (mm) (if applicable).
—Material wrapper basis weight (g/m^2) (if applicable).
—Material porosity or permeability (CU) (if applicable).
—Heating element:
—Heating element diameter (gauge) (if applicable).
—Heating element resistance (Ohms) (if applicable).
—Heating element temperature range (°C).
—E-liquid:
—E-liquid viscosity (at 20 °C) (if applicable).
—E-liquid volume (ml) (if applicable).
—Tobacco:
—Tobacco moisture or oven volatiles (%) (if applicable).
—Tobacco cut size (CPI or mm) (if applicable).
—Tobacco density (g/cm^3) (if applicable).
—Battery:
—Battery voltage operating range (V) or wattage (W).
—Battery current operating range (mA).
—PDU voltage operating range (V).
—PDU current operating range (mA).
—PDU wattage operating range (watts).
—PDU current cut-off (mA) (if applicable).
—PDU temperature cut-off (°C) (if applicable).
—Battery capacity (mAh).
—Battery nominal voltage (V).
—Battery current rating (mA).
—Battery charging temperature limits (°C).
—Battery discharge temperature limits (°C).

TABLE 42 TO § 1107.19(a)(21)—Continued

—Battery maximum charging current (mA).
—Battery maximum discharging current (mA).
—Battery upper limits charging voltage (V).
—Aerosol:
—Inhaled aerosol temperature (°C).
—Aerosol particle number concentration (#/cm^3).
—Count median diameter (nm).
—$PM_{2.5}$ (µg/m^3).
—Filter (if applicable):
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the filter is unchanged (*e.g.,* DPF, total denier (g/9000m), and filter density(g/cm^3))).
—Filter ventilation (%).
—Filter pressure drop (mm H_2O).

(b) *Comparison of heating sources.* The SE Report must include a description of the heating source for the new and predicate tobacco products and identify any differences, or state that there is no heating source.

(c) *Comparison of product composition.* The SE Report must include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. For each material and ingredient quantity, the target specifications and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part, must be provided.

(1) *Materials.* For each material in the products include:

(i) The material name and common name(s), if applicable;

(ii) The component or part of the tobacco product where the material is located;

(iii) The subcomponent or subpart where the material is located, if applicable;

(iv) The function of the material;

(v) The quantities (including ranges or means, acceptance limits) of the material(s) in each new tobacco product and predicate tobacco product (with any specification variation, if applicable);

(vi) The specification(s) (including quality/grades, suppliers) used for the new tobacco product and predicate tobacco product (with any specification variations, if applicable); and

(vii) Any other material properties necessary to characterize the new and predicate tobacco products.

(2) *Ingredients other than tobacco.* For each ingredient other than tobacco in each material or component or part of the product include:

(i) The International Union of Pure and Applied Chemistry (IUPAC) chemical name and common name, if applicable;

(ii) The Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredient Identifier (UNII);

(iii) The function of the ingredient;

(iv) The quantity with the unit of measure (including ranges or means, acceptance limits) of the ingredient in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products (with any specification variation, if applicable);

(v) The specification(s) (including purity or grade and supplier);

(vi) For complex purchased ingredients, each single chemical substance reported separately; and

(vii) Any other ingredient information necessary to characterize the new and predicate tobacco products.

(3) *Tobacco ingredients.* For tobacco include:

(i) The type (*e.g.*, Bright, Burley, reconstituted);

(ii) The curing method (*e.g.*, flue cured, dark air cured);

(iii) The quantity of each type with the unit of measure (including ranges or means, acceptance limits) of tobacco in the new tobacco product and predicate tobacco product reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products;

(iv) A description of any genetic engineering of the tobacco; and

(v) Any other information necessary to characterize the new and predicate tobacco products.

(vi) If the new tobacco product does not contain tobacco, then include a statement that the new tobacco product does not contain tobacco.

(4) *Container closure system.* A description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the components and materials and annotated illustrations.

(d) *Comparison of other features.* The SE Report must include descriptions of any other features of the new and predicate tobacco products, such as those described in paragraphs (d)(1) and (2) of this section, and identify any differences. If a specific feature specified in paragraphs (d)(1) and (2) of this section is not applicable to the product design, this must be stated clearly. If FDA requests a scientific justification explaining why a feature is not applicable, the applicant must provide the justification to FDA. The comparison of other features must include information on:

(1) *Constituents.* HPHCs and other constituents, as appropriate, to demonstrate that:

(i) The new tobacco product has the same characteristics as the predicate tobacco product, or

(ii) Any differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health, including:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number(s);

(D) The mean quantity and variance with unit of measure;

(E) The number of samples and measurement replicates for each sample;

(F) The analytical methods used, associated reference(s), and full validation reports for each analytical method;

(G) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(H) Length of time between dates of manufacture and date(s) of testing;

(I) Storage conditions of the tobacco product before it was tested;

(J) Reference product datasets (if applicable);

(K) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria and complete data sets) for all testing performed. Test data for combusted or inhaled tobacco products must reflect testing conducted using both intense and non-intense smoking or aerosol-generating regimens, where established; and

(L) Complete descriptions of any smoking or aerosol-generating regimens used for analytical testing that are not standardized or widely accepted by the scientific community, if applicable.

(2) *Any other features.* A description and comparison of any other features of the new tobacco product and the predicate tobacco product.

(e) *Comparison of tobacco processing.* The SE Report must include information on the tobacco processes in paragraphs (e)(1) and (2) of this section for the new and predicate tobacco products, if applicable, and identify any differences.

(1) *Fermentation process.* For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), the SE Report must contain the following information regarding the fermentation process of the new and predicate tobacco products and identify any differences:

(i) Description of the fermentation process;

(ii) Composition of the inoculum (starter culture) with genus and species name(s) and concentration(s) (if applicable);

(iii) Any step(s) taken to reduce microbes already present during processing (*e.g.*, cleaning of contact surfaces);

(iv) Specifications and test data for pH, temperature, and moisture content or water activity;

(v) Frequency of aeration or turning (if applicable);

(vi) Duration of fermentation;

(vii) Added ingredients;

(viii) Method used to stabilize or stop fermentation ((*e.g.*, heat treatment), if applicable), including parameters of the method (*e.g.*, length of treatment, temperature) and method validation data; and

(ix) Storage conditions of the fermented tobacco prior to further processing or packaging and duration of storage (if applicable).

(2) *Heat treatment process*. For tobacco products that are heat treated, the SE Report must contain the following information regarding the heat treatment process of the new and predicate tobacco products and identify any differences:

(i) Description of the heat treatment process;

(ii) Type of heat treatment;

(iii) Conditions of heat treatment, including time, temperature, and moisture; and

(iv) Method validation data, including microbial loads (including bacteria, spores, yeast and fungi) and tobacco-specific nitrosamines (TSNAs) before and after heat treatment.

(f) *Shelf life and stability information*. With the exception of SE Reports for roll-your-own tobacco products and cigarettes that are not HTPs, SE Reports for all tobacco products must contain information on the stability of the new and predicate tobacco products over the shelf life, including the following information:

(1) The length of the shelf life, a description of how shelf life is determined, and a description of how shelf life is indicated on the tobacco product, if applicable. If a tobacco product does not have a defined shelf life, state as such;

(2) Any known or expected impacts of the differences between the new and predicate products on the product stability. If no impact is known or expected, state that;

(3) Stability data assessed at the beginning (zero time), middle, and end of the expected shelf life. If a tobacco product does not have a defined shelf life, provide stability data over a specified amount of time and a justification for why that time period is appropriate. Stability testing must be performed for the microbial and chemical endpoints as follows:

(i) Microbial content data including total aerobic microbial count and total yeast and mold count;

(ii) Water activity; and

(iii) Tobacco-specific nitrosamine yields (total, N-nitrosonornicotine (NNN), and 4-methylnitrosamino)-1-(3-pydridyl)-1-butanone) (NNK)).

(4) Stability testing details for each microbial and chemical endpoint, including:

(i) The mean quantity and variance with unit of measure;

(ii) The number of samples and measurement replicates for each sample;

(iii) The methods used, associated reference(s), and full validation reports for each method (as applicable);

(iv) The testing laboratory or laboratories and documentation showing that the laboratory or laboratories is (or are) accredited by a nationally or internationally recognized external accreditation organization;

(v) Length of time between dates of tobacco product manufacture and date(s) of testing;

(vi) Storage conditions of the tobacco products before they were tested;

(vii) A statement that the testing was performed on a tobacco product in the same container closure system in which the tobacco product is intended to be marketed; and

(viii) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, complete data sets, and a summary of the results) for all stability testing performed.

(g) *Applicant's basis for substantial equivalence determination*. The applicant

must state that the new tobacco product has either:

(1) The same characteristics as the predicate tobacco product and the basis for this determination, or

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (paragraph (a) of this section); heating source (paragraph (b) of this section); materials and ingredients (paragraph (c) of this section); and other features (paragraph (d) of this section). In addition, to demonstrate that a new tobacco product is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product would not change the characteristics of the new tobacco product such that the new tobacco product could raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products and tobacco products that contain fermented tobacco, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not cause the new tobacco product to raise different questions of public health (paragraph (f) of this section).

(h) *Comparison to original predicate tobacco product.* If the applicant is comparing the new tobacco product to a predicate tobacco product that FDA has previously found to be substantially equivalent, FDA may request that the applicant include information related to the original predicate tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, even if that original predicate tobacco product is back several predicate tobacco products. FDA will request this information when necessary to ensure that any order the Agency issues finding the new tobacco product substantially equivalent complies with section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act. FDA may need to review the first SE Report that received a finding of substantial equivalence using the original predicate tobacco product as a predicate tobacco product in order to make this finding.

§ 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter.

(b) An applicant may not amend an SE Report to change the predicate tobacco product.

(c) An applicant may not amend an SE Report after FDA has closed the SE Report under § 1107.44 or it has been withdrawn under § 1107.22.

(d) In general, amendments will be reviewed in the next review cycle as described in § 1107.42.

§ 1107.22 Withdrawal by applicant.

(a) An applicant may at any time make a written request to withdraw an SE Report for which FDA has not issued an order. The withdrawal request must state:

(1) Whether the withdrawal is due to a health or safety concern related to the tobacco product;

(2) The submission tracking number; and

(3) The name of the new tobacco product that is the subject of the SE Report.

(b) An SE Report will be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn.

(c) The SE Report is an Agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The

availability of the withdrawn SE Report will be subject to FDA's public information regulations in part 20 of this chapter.

§ 1107.24 Change in ownership of an SE Report.

An applicant may transfer ownership of its SE Report. On or before the time of transfer, the new and former applicants are required to submit information to FDA as follows:

(a) The former applicant must sign and submit a notice to FDA that states that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. This notice must identify the name and address of the new applicant and the SE Report transferred.

(b) The new applicant must sign and submit a notice to FDA containing the following:

(1) The new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under §1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in §20.45 of this chapter; and

(4) A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

Subpart D—FDA Review

SOURCE: 86 FR 55275, Oct. 4, 2021, unless otherwise noted.

§ 1107.40 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an SE Report, FDA may communicate with applicants about relevant matters, including scientific, medical, and procedural issues that arise during the review process. These communications may take the form of telephone conversations, letters, or emails, and will be documented in the SE Report in accordance with §10.65 of this chapter.

(b) *Meeting.* Meetings between FDA and applicants may be held to discuss scientific and other issues. Requests for meetings will be directed to the Office of Science, Center for Tobacco Products, and FDA will make every attempt to grant requests for meetings that involve important issues.

(c) *Acceptance of an SE Report for review.* After receiving an SE Report under §1107.18, FDA will either refuse to accept the SE Report for review or issue an acceptance for review letter.

(d) *Notification of deficiencies in an SE Report submitted under §1107.18.* FDA will make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and any additional information and data needed for the Agency's review. The applicant must also provide additional comparison information under §1107.19 if requested by FDA.

(e) *Withdrawal of SE Report.* An SE Report will be considered withdrawn when FDA issues a notice stating that the SE Report has been withdrawn.

§ 1107.42 Review cycles.

(a) *Initial review cycle.* FDA intends to review the SE Report and either communicate with the applicant as described in §1107.40 or take an action under §1107.44 within 90 calendar days of FDA's receipt of the SE Report, or within 90 calendar days of determining that the predicate was found to be commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (if applicable), whichever is later. This 90-day period is called the ''initial review cycle.''

(b) *Additional review cycles.* If FDA issues a deficiency notification under §1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the

applicant fails to respond within the time period provided in the notification of deficiency, FDA will issue an order denying marketing authorization under the criteria set forth in §1107.48. If the applicant's response to the notification of deficiencies provides the information FDA requested, but FDA identifies additional deficiencies, FDA may issue an additional deficiency notification. Each response will begin a new 90-day review cycle.

(c) *Inadequate response.* If the applicant's response to FDA's deficiency notification(s) does not provide the information FDA requested, or the applicant provides information but the SE Report is still deficient, FDA generally intends to issue an order denying market authorization under the criteria set forth in §1107.48. At any time before FDA issues an order, an applicant may make a written request to withdraw an SE Report under §1107.22.

§1107.44 FDA action on an SE Report.

After receipt of an SE Report, FDA will:

(a) Refuse to accept the SE Report for review if it does not comply with §1107.18 and §1105.10 of this chapter;

(b) Request additional information as provided in §1107.40(d);

(c) Issue a letter administratively closing the SE Report if it is not possible to make a determination on an SE Report;

(d) Issue a letter canceling the SE Report if FDA finds the SE Report was created in error;

(e) Issue an order as described in §1107.46 finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act; or

(f) Issue an order as described in §1107.48 denying marketing authorization because the new tobacco product is:

(1) Not substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States on February 15, 2007, or

(2) Not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

§1107.46 Issuance of an order finding a new tobacco product substantially equivalent.

If FDA finds that the information submitted in the SE Report establishes that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007, and finds that the new tobacco product is in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, FDA will send the applicant an order authorizing marketing of the new tobacco product. A marketing authorization order becomes effective on the date the order is issued.

§1107.48 Issuance of an order denying marketing authorization.

(a) *General.* FDA will issue an order that the new tobacco product cannot be marketed if FDA finds that:

(1) The information submitted in the SE Report does not establish that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed (other than for test marketing) in the United States on February 15, 2007; or

(2) The new tobacco product is not in compliance with the Federal Food, Drug, and Cosmetic Act.

(b) *Basis for order.* The order will describe the basis for denying marketing authorization.

§1107.50 Rescission of order.

(a) *Grounds for rescinding a substantially equivalent order.* FDA may rescind a substantially equivalent order allowing a new tobacco product to be marketed if FDA determines that:

(1) The tobacco product for which the order has been issued:

(i) Does not have the same characteristics as the predicate tobacco product; or

(ii) Has different characteristics and there is insufficient information demonstrating that it is not appropriate to require a premarket tobacco product application under section 910(b) of the Federal Food, Drug, and Cosmetic Act because the product does not raise different questions of public health; or

(2) The SE Report (including any submitted amendments) contains an untrue statement of material fact; or

(3) Concerning an SE Report that compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent,

(i) The predicate tobacco product relied on in the SE Report has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations was based, going back to the original predicate tobacco product, has been found ineligible because its SE Report (including any amendments) contains an untrue statement of material fact; or

(4) FDA or the applicant has removed from the market, due to a health or safety concern related to the tobacco product:

(i) The predicate tobacco product on which the substantial equivalence determination is based; or

(ii) A predicate tobacco product on which any of the previous substantial equivalence determinations is based, going back to the original predicate tobacco product, if the substantial equivalence SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent.

(b) *Opportunity for a hearing.* (1) Except as provided in paragraphs (b)(2) and (3) of this section, FDA will rescind an order only after notice and opportunity for a hearing under part 16 of this chapter.

(2) FDA may rescind a substantially equivalent order prior to notice and opportunity for a hearing under part 16 of this chapter if it finds that there is a reasonable probability that continued marketing of the tobacco product presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

(3) FDA may rescind a substantially equivalent order without notice and opportunity for a hearing under part 16 of this chapter if the applicant has notified the Agency of a mistake in the application, FDA has determined that the mistake is part of the underlying scientific determination of the order which makes the order invalid, and the applicant has agreed that FDA can rescind the order without providing notice and opportunity for a hearing under part 16 of this chapter.

Subpart E—Miscellaneous

SOURCE: 86 FR 55275, Oct. 4, 2021, unless otherwise noted.

§ 1107.58 Record retention.

Each applicant that receives an order under §1107.46 authorizing the marketing of a new tobacco product must maintain all records required by this subpart and that support the SE Report for a substantial equivalence order. These records must be legible, in the English language, and available for inspection and copying by officers or employees duly designated by the Secretary. All records must be retained for a period of not less than 4 years from the date of the order even if such product is discontinued.

§ 1107.60 Confidentiality.

(a) *General.* FDA will determine the public availability of any part of an SE Report and other content related to such an SE Report under this section and part 20 of this chapter.

(b) *Confidentiality of data and information prior to an order.* Prior to issuing an order under this section:

(1) FDA will not publicly disclose the existence of an SE Report unless:

(i) The tobacco product has been introduced or delivered for introduction into interstate commerce for commercial distribution; or

(ii) The applicant has publicly disclosed or acknowledged the existence of the SE Report (as such disclosure is defined in §20.81 of this chapter), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA.

(2) FDA will not disclose the existence of or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents

of that particular FDA communication.

(3) FDA will not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

(c) *Disclosure of data and information after issuance of an order under § 1107.46.* After FDA issues an order under § 1107.46 finding a new tobacco product substantially equivalent, it will make the following information related to the SE Report and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the SE Report and FDA's reviews of the SE Report:

(1) All data previously disclosed to the public, as such disclosure is defined in § 20.81 of this chapter;

(2) Any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter;

(3) Information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy;

(4) Correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 of this chapter for trade secrets and confidential commercial information, or in § 20.63 of this chapter for personal privacy; and

(5) In accordance with § 25.51 of this chapter, the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter.

(d) *Disclosure of data and information after issuance of an order under § 1107.48.* After FDA issues an order under § 1107.48 (denying marketing authorization), FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes the tobacco product category (*e.g.*, cigarette), tobacco product subcategory (*e.g.*, filtered), package size, and the basis for the order denying marketing authorization.

(e) *Health information summary or statement.* Health information required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act, if submitted as part of the SE Report (which includes any amendments), will be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA will make publicly available on FDA's website the responsible official to whom a request for health information may be made.

§ 1107.62 Electronic submission.

(a) *Electronic format requirement.* Applicants submitting any documents to the Agency under this part must provide all required information to FDA using the Agency's electronic system, except as provided in paragraph (b) of this section. The SE Report and all supporting information must be in an electronic format that FDA can process, read, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request

to the address included on our website (*www.fda.gov/tobaccoproducts*). The request must include the following information:

(1) The name and address of the applicant, list of individuals authorized for the applicant to serve as the contact person, and contact information including an email address. If the applicant has submitted an SE Report previously, the regulatory correspondence must also include any identifying information for the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the person requesting the waiver, and an explanation of why creation and/or submission in electronic format is not reasonable. This statement must be signed by the applicant or by an employee of the applicant who is authorized to make the declaration on behalf of the applicant.

(c) *Paper submission.* An applicant who has obtained a waiver from filing electronically must send a written SE Report through the Document Control Center to the address provided in the FDA documentation granting the waiver.

PART 1114—PREMARKET TOBACCO PRODUCT APPLICATIONS

Subpart A—General Provisions

Subpart B—Premarket Tobacco Product Applications

Subpart C—FDA Review

Subpart D—Postmarket Requirements

Subpart E—Miscellaneous

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

SOURCE: 86 FR 55412, Oct. 4, 2021, unless otherwise noted.

Subpart A—General Provisions

§ 1114.1 Scope.

(a) This part sets forth the procedures and requirements for submitting a premarket tobacco product application (PMTA), the general procedures FDA will follow when evaluating a PMTA, and postmarket reporting requirements.

(b) This part does not apply to modified risk tobacco product applications, except that single applications seeking both a marketing granted order under section 910(c) of the Federal Food, Drug, and Cosmetic Act and an order under section 911(g) of the Federal Food, Drug, and Cosmetic Act must satisfy the requirements of this part in addition to the requirements of section 911 of the Federal Food, Drug, and Cosmetic Act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(d) This part does not apply to ''premium'' cigars as defined in §1114.3.

§ 1114.3 Definitions.

For 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: