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:

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

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

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

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

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 such term does not include tobacco, or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

Adverse experience means any unfavorable physical or psychological effect in a person that is temporally associated with the use of or exposure to a tobacco product, whether or not the person uses the tobacco product, and whether or not the effect is considered to be related to the use of or exposure to the tobacco product.

Applicant means any person that submits a premarket tobacco product application to receive a marketing granted order 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.

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

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 product, including through combustion or heating of tobacco, additives, or other components 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.

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 e-liquids sealed in final packaging sold to consumers either 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 or *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.

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.

Label means a display of written, printed, or graphic matter upon the immediate container of any article.

Labeling means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

Line data means an analyzable dataset of observations for each individual study participant, laboratory animal, or test replicate.

Marketing denial order means the order described in section 910(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act stating that the product may not be introduced or delivered for introduction into interstate commerce.

Marketing granted order means the order described in section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act stating that the new tobacco product may be introduced or delivered for introduction into interstate commerce.

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

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.

Premarket tobacco product application or *PMTA* means the application described in section 910(b) of the Federal Food, Drug, and Cosmetic Act. This term includes the initial premarket tobacco product application and all subsequent amendments.

''Premium'' cigar 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.

Serious adverse experience means an adverse experience that results in any of the following outcomes:

(1) Death;

(2) A life-threatening condition or illness;

(3) Inpatient hospitalization or prolongation of existing hospitalization;

(4) A persistent or significant incapacity or substantial disruption of the

ability to conduct normal life functions;

(5) A congenital anomaly/birth defect; or

(6) Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from an applicant, such as a PMTA and a supplemental PMTA.

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.

Unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

(1) The known or foreseeable risks of adverse experiences associated with the use or exposure to the tobacco product as described in the PMTA and other relevant sources of information, such as the product labeling and postmarket reports;

(2) The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or

(3) The results of nonclinical investigations.

Vulnerable populations means groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Vulnerable populations can include, but are not limited to, youth and young adults, those with lower socioeconomic status, certain races or ethnicities, sexual or gender minorities, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, and those with mental health conditions or substance use disorders.

[86 FR 55412, Oct. 4, 2021, as amended at 88 FR 16553, Mar. 20, 2023]

Subpart B—Premarket Tobacco Product Applications

§ 1114.5 Application submission.

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing granted order for the product.

§ 1114.7 Required content and format.

(a) *General.* The PMTA must contain sufficient information for FDA to determine whether any of the grounds for marketing denial order specified in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. The application must contain the following sections:

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

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

(3) Product samples (as described in paragraph (e) of this section);

(4) Labeling and description of marketing plans (as described in paragraph (f) of this section);

(5) Statement of compliance with 21 CFR part 25 (as described in paragraph (g) of this section);

(6) Summary (as described in paragraph (h) of this section);

(7) Product formulation (as described in paragraph (i) of this section);

(8) Manufacturing (as described in paragraph (j) of this section);

(9) Health risk investigations (as described in paragraph (k) of this section); and

(10) The effect on the population as a whole (as described in paragraph (l) of this section);

(11) Certification statement (as described in paragraph (m) of this section).

(b) *Format.* (1) The application must be submitted using the form(s) that FDA provides, contain a comprehensive index (*i.e.*, a listing of files and data associated with those files) and table of contents, be well-organized and legible, and be written in English. Documents that have been translated from another language into English (*e.g.*, original study documents written in a language other than English) must be accompanied by: The original language version of the document, signed a 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. As described in §1114.49, the applicant must submit the application and all information supporting the application in an electronic format that FDA can process, read, review, and archive, unless FDA has granted a waiver.

(2) An applicant may include content in a submission by cross-reference to a tobacco product master file or a pending modified risk tobacco product application for the same tobacco product. Applicants using a master file must provide documentation of their right of reference for the master file and clearly identify the specific content being incorporated into the PMTA submission. Except as provided for in §§1114.15 and 1114.17, FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *General information.* The applicant must, by using the form(s) FDA provides, specify the following general information:

(1) Applicant name, address, and contact information;

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

(3) The following information to uniquely identify the product:

(i) Manufacturer;

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

(iii) The product category, product subcategory, and product properties as provided in the following table. If the product does not have a listed product property, such as ventilation or characterizing flavor, the application must state ''none'' for that property.

TABLE 1 TO PARAGRAPH (c)(3)(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), 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*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, 100.0 mm). —Diameter (e.g., 6.0 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).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Length (e.g., 89.1 mm, 100.0 mm).
		—Diameter (e.g., 6.0 mm, 8.1 mm).
		—Ventilation (e.g., none, 10.0%, 25.0%).
		—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], 16.0 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, 100.0 mm, 110.2 mm).
		—Width (e.g., 28.1 mm, 33.0 mm, 45.2 mm).
		—Characterizing flavor(s) (e.g., none, menthol).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Cigarette Tube, Filtered.	—Package type (e.g., bag, box).
		—Product quantity (e.g., 100 tubes, 200 tubes).
		—Length (e.g., 89.1 mm, 100.0 mm).
		—Diameter (e.g., 6.0 mm, 8.1 mm).
		—Ventilation (e.g., none, 10.0%, 25.0%).
		—Characterizing flavor(s) (e.g., none, menthol, tobacco).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Cigarette Tube, Non-filtered.	—Package type (e.g., bag, box).
		—Product quantity (e.g., 100 tubes, 200 tubes).
		—Length (e.g., 89.1 mm, 100.0 mm).
		—Diameter (e.g., 6.0 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., 8.0 mm, 12.1 mm).
		—Diameter (e.g., 6.0 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., 12.0 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).
		—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*) Moist Snuff, Loose.	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).
		—Product quantity (e.g., 20.0 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*) Moist Snuff, Portioned.	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).
		—Product quantity (e.g., 22.5 g, 20.0 g).
		—Portion count (e.g., 15 pouches, 20 pieces).
		—Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece).
		—Portion length (e.g., 15.0 mm, 20.1 mm).
		—Portion width (e.g., 10.0 mm, 15.1 mm).
		—Portion thickness (e.g., 5.0 mm, 7.1 mm).
		—Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen).
		—Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	(*3*) Snus, Loose	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20.0 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*) Snus, Portioned	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 1.0 g/piece). —Portion length (e.g., 15.0 mm, 20.1 mm). —Portion width (e.g., 10.0 mm, 15.1 mm). —Portion thickness (e.g., 5.0 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*) Dry Snuff, Loose	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20.0 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, 20.0 g) —Portion count (e.g., 15 sticks, 20 pieces). —Portion mass (e.g., 1.5 g/strip, 1.0 g/piece). —Portion length (e.g., 10.0 mm, 15.1 mm). —Portion width (e.g., 5.0 mm, 8.1 mm). —Portion thickness (e.g., 3.0 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*) Chewing Tobacco, Loose.	—Package type (e.g., bag, pouch, wrapped). —Product quantity (e.g., 20.0 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*) Chewing Tobacco, Portioned.	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20.0 g) —Portion count (e.g., 10 bits). —Portion mass (e.g., 2.1 g/bit). —Portion length (e.g., 8.0 mm, 10.1 mm). —Portion width (e.g., 6.0 mm, 8.1 mm). —Portion thickness (e.g., 5.1 mm, 7.0 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., bag, box, can). —Product quantity (e.g., 20.1 g, 22.5 g, 3.0 oz.). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen, tobacco). —Additional properties needed to uniquely identify the tobacco product.
(D) Electronic Nicotine Delivery System (ENDS) (Also referred to as vapes).	(*1*) E-Liquid, Open ..	—Package type (e.g., bottle, box, pod). —Product quantity (e.g., 1 bottle, 5 bottles). —E-liquid volume (e.g., 0.5 milliliters [ml]), 2.0 ml, 5.1 ml). —Nicotine concentration (e.g., 0 milligrams/milliliter [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*) E-Liquid, Closed	—Package type (e.g., cartridge, pod). —Product quantity (e.g., 1 cartridge, 5 cartridges). —E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml). —Nicotine concentration (e.g., 0 mg/ml, 0.2 mg/ml, 0.4 mg/ml, 1%, 2.0 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).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) E-Cigarette, Closed.	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Length (e.g., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 mm, 8.0 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, 2.0 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.
	(*4*) E-Cigarette, Open.	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Length (e.g., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 mm, 8.0 mm). —E-liquid volume (e.g., 0.5 ml, 2.0 ml, 5.1 ml). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —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, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) ENDS Other	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 bottles). —Characterizing flavor(s) (e.g., none, cherry, wintergreen, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	(*1*) Cigar, 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, 100.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 0%, 10.0%, 25.0%). —Characterizing flavor (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Cigar, Unfiltered Sheet-Wrapped.	—Package type (e.g., box, film sleeve). —Product quantity (e.g., 1 cigar, 5 cigarillos). —Length (e.g., 100.1 mm, 140.0 mm). —Diameter (e.g., 8.0 mm, 10.1 mm). —Tip (e.g., none, wood tips, plastic tips). —Characterizing flavor (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Cigar, Unfiltered Leaf-Wrapped.	—Package type (e.g., box, film, sleeve, none). —Product quantity (e.g., 1 cigar, 5 cigars). —Length (e.g., 150.1 mm, 200.0 mm). —Diameter (e.g., 8.0 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).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Product quantity (e.g., 20.0 g, 16.1 oz.). —Characterizing flavor (e.g., none, 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., 200.0 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., bag, none). —Product quantity (e.g., 20.0 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., bag, box, 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., 200.0 mm, 500.1 mm). —Width (e.g., 100.1 mm, 300.0 mm). —Diameter (e.g., 100.1 mm, 300.0 mm)—Number 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., 20.0 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). —Product quantity (e.g., 150.0 g, 680.0 g). —Portion count (e.g., 20 fingers, 10 discs, 1 base). —Portion mass (e.g., 15.0 g/finger, 10.0g/brick). —Portion length (e.g., 40.0 mm, 100.0 mm). —Portion width (e.g., 10.0 mm, 40.0 mm). —Portion thickness (e.g., 10.0 mm, 40.0 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., bag, box, none). —Product quantity (e.g., 1 base, 1 bowl, 1 hose, 10 mouthpieces). —Characterizing flavor(s) (e.g., none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Waterpipe Other	—Package type (e.g., bag, box, 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).

TABLE 1 TO PARAGRAPH (c)(3)(iii)—Continued

Tobacco product category	Tobacco product subcategory	Product properties
(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., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 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., 100.0 mm, 120.0 mm). —Diameter (e.g., 6.0 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., 60.0 mm, 82.0 mm). —Diameter (e.g., 6.0 mm, 8.1 mm). —Ventilation (e.g., none, 10.0%, 25.0%). —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).
(I) Other	(*1*) 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).

(4) The type of PMTA (*i.e.*, PMTA, supplemental PMTA, or resubmission);

(5) Whether the applicant requests that FDA refer the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC);

(6) Identifying information regarding any prior submissions regarding the tobacco product (*e.g.*, submissions related to investigational tobacco products, substantial equivalence reports, PMTAs), including submission tracking numbers (STNs) where applicable;

(7) Dates and purpose of any prior meetings with FDA regarding the new tobacco product;

(8) If applicable, the dates when the tobacco product was commercially marketed in the United States;

(9) Address and the Facility Establishment Identifier (FEI) number(s), if available, of the establishment(s) involved in the manufacture of the new tobacco product;

(10) A brief statement regarding how the PMTA satisfies the content requirements of section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act;

(11) A brief description of how marketing of the new tobacco product would be appropriate for the protection of the public health; and

(12) A list identifying all enclosures, labels, and labeling being submitted with the application.

(d) *Descriptive information.* The application must contain descriptive information in this section that outlines

the major aspects of the new tobacco product, including the following items:

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

(2) A statement identifying all tobacco product standards issued under section 907 of the Federal Food, Drug, and Cosmetic Act that are applicable to the new tobacco product and a brief description of how the new tobacco product fully meets any identified tobacco product standard, or if the new tobacco product deviates from a product standard, if applicable, the application must include adequate information to identify and justify those deviations;

(3) The name(s) of the product as designated on the product's label;

(4) A description of problems that were identified in prototypes that are the subject of studies in the application and previous or similar versions of the new tobacco product that were marketed, if any. If there are previous or similar versions that are the subject of studies in the application or were marketed, the application must contain a bibliography of all reports regarding the previous or similar version of the product, whether adverse or supportive; and

(5) Any restrictions on the sale, distribution, advertising, or promotion of the new tobacco product that the applicant proposes to be included as part of a marketing granted order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to help support a showing that the marketing of the product is appropriate for the protection of the public health. If there are no proposed restrictions, the application must contain a statement to that effect.

(e) *Samples of new tobacco products.* After FDA accepts a PMTA for review, it may require the submission of samples of the new tobacco product, including its components and parts. If required, the applicant must submit samples of the finished tobacco product or its components or parts in accordance with instructions provided by FDA. FDA may also require the submission of additional samples to further aid in its review.

(f) *Labeling and description of marketing plans*—(1) *Labeling.* The application must contain specimens of all proposed labeling for the new tobacco product, including labels, inserts, onserts, instructions, and other accompanying information. The specimens of labeling must include all panels, reflect the actual size and color proposed to be used for the tobacco product, and include any warning label statements and other information required by regulation or statute, as applicable.

(2) *Description of Marketing Plans.* A PMTA must contain a description of the applicant's plans to market the new tobacco product, for at least the first year the product would be marketed after receiving a marketing granted order, in way that is both consistent with the applicant's discussion of the increased or decreased likelihood of changes in tobacco product use behavior, including switching, initiation, cessation, and polyuse, under §1114.7(l), and permits FDA to determine permitting the new tobacco product to be marketed would be appropriate for the protection of public health. The description must include actions to market the product that would be taken by the applicant, on behalf of the applicant, or at the applicant's direction, and also discuss any restrictions on the sales and distribution the applicant proposes to be included in a marketing order under section 910(c)(1)(B) of the Federal Food Drug and Cosmetic Act. The description of marketing plans must contain, at minimum:

(i) A description of the specific group(s) to which the labeling, advertising, marketing, promotion, and other consumer-directed activities for the new tobacco product would be targeted (*i.e.*, the intended audience(s));

(ii) A discussion of how the labeling, advertising, marketing, promotion, and other consumer-directed activities for the new tobacco product would be targeted to reach the intended audience(s) identified in paragraph (i) and what other group(s) would foreseeably be exposed to those materials and activities as a result;

(iii) A discussion of, for individuals below the minimum age of sale, how access to the new tobacco product would be restricted and exposure to the

labeling, advertising, marketing, promotion, and other consumer-directed activities would be limited; and

(iv) A concluding summary describing how the applicant's plans for marketing the new tobacco product are consistent with the applicant's discussion of the increased or decreased likelihood of changes in tobacco product use behavior, including switching, initiation, cessation, and polyuse, under § 1114.7(l) and permits FDA to determine permitting the new tobacco product to be marketed would be appropriate for the protection of public health.

(g) *Statement of compliance with 21 CFR part 25.* (1) The application must contain an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion, if applicable. 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 of this chapter.

(h) *Summary.* The application must include a summary of all information contained in the application. The summary must include the following items, highlighting the effects on youth, young adults, and other relevant vulnerable populations:

(1) A summary of the product formulation section of the application;

(2) A summary of the manufacturing section of the application;

(3) A summary of the health risk investigations section of the application, including all information regarding the following items, and identify areas in which there is a lack of information, where applicable:

(i) The health risks of the tobacco product to both users and nonusers of the product and whether the tobacco product may present less health risk than other tobacco products;

(ii) The impact the product and its marketing will have on the likelihood of changes in tobacco use behavior, including cessation, switching, and polyuse, of tobacco product users;

(iii) The impact the product and its marketing will have on the likelihood of tobacco use initiation by tobacco product nonusers;

(iv) How users and nonusers perceive the risk of the tobacco product based upon its label, labeling, and advertising, to the extent that advertising has been studied;

(v) Whether users are able to understand the labeling and instructions for use, and use the product in accordance with those instructions; and

(vi) The impact of human factors on the health risks to product users and nonusers (as described in paragraph (k)(1)(v) of this section);

(4) A concluding discussion describing how the data and information contained in the PMTA both constitute valid scientific evidence and establish that permitting marketing of the new tobacco product is appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product. This discussion must specifically describe the effects on youth, young adults, and other relevant vulnerable populations with an emphasis on populations that are most likely to use the new tobacco product. The summary must also identify any key or pivotal studies on which an applicant is relying to establish that permitting the marketing of the new tobacco product would be APPH.

(i) *Product formulation.* The application must contain a full statement of the components or parts, materials, ingredients, additives, constituents, properties, and the principle or principles of operation, of the tobacco product, including the following information:

(1) *Components or parts, materials, ingredients, additives, and constituents.* The applicant must provide a full statement of:

(i) *Components or parts.* The quantity, function, and purpose of, and, where applicable, target specification(s) of, each component or part in the product. Where the tobacco product contains software components, the applicant must provide:

(A) A description of the software or technology (*e.g.*, Bluetooth);

(B) The purpose of the software or technology, such as monitoring where tobacco products are located, activated, or used;

(C) A description of the data collected by the software and how it will be used.

(ii) *Materials.* For each material in the product, include:

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

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

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

(D) The function of the material;

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

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

(G) Any other material properties to fully characterize the new tobacco product.

(iii) *Ingredients other than tobacco.* For ingredients other than tobacco in each component or part of the product, include:

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

(B) The Chemical Abstracts Service (CAS) number or FDA Unique Ingredient Identifier (UNII), if applicable;

(C) The function of the ingredient;

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

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

(F) For complex purchased ingredients, each single chemical substance reported separately.

(iv) *Tobacco ingredients.* For tobacco ingredients in each component or part, include the following information or, if applicable, a statement that the product does not contain tobacco ingredients:

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

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

(C) The specification of tobacco used for the new tobacco product (with any specification variation, if applicable); and

(D) A description of any genetic engineering of the tobacco that impacts product characteristics.

(v) *Constituents.* Constituents, including HPHCs and other constituents, contained within, or emitted from (including its smoke or aerosol), the product, including any reaction product from leaching or aging, by providing:

(A) The constituent names in alphabetical order;

(B) The common name(s);

(C) The Chemical Abstract Services number;

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

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

(F) A description of method procedure, method validation information and rationale for selecting each test method;

(G) The name and location of 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) Test data including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria, and line data for all testing performed. Test data for combusted or inhaled products must reflect testing conducted using both intense

and nonintense smoking or aerosol-generating regimens, where established; and

(K) 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.

(vi) *Container closure system.* A description of the container closure system, including:

(A) Information describing how the container closure system protects and preserves the product from damage during transport, environmental contaminants, and potential leaching and migration of packaging constituents into the new tobacco product; and

(B) Information describing design features developed to prevent the risk of accidental exposure, if any.

(vii) *Statement of tobacco blending, reconstitution, or manipulation.* Information regarding tobacco blending, reconstitution, or manipulation, where applicable.

(2) *Other properties.* The applicant must provide a full description of the additional properties of the tobacco product that includes:

(i) *Product dimensions and construction.* The product dimensions and the overall construction of the product using a diagram or schematic drawing that clearly depicts the finished tobacco product and its components with dimensions, operating parameters, and materials.

(ii) *Design parameters and test data.* (A) All final design parameters of the product, specifying nominal values or the explicit range of values as well as the design tolerance (where appropriate), including, but not limited to, the parameters specified in tables 1 to 22 of this paragraph as applicable. If a design parameter specified in tables 1 to 22 does not apply to the tobacco product, applicants must explain why the required design parameter does not apply or how an alternative design parameter would satisfy the required design parameter. If the product has additional design parameters that are not specified in tables 1 to 22, the application must contain a description of the design specifications as well as test data and processes to demonstrate that the design parameters and their associated processes are adequately controlled; and

(B) A quantitative description of the performance criteria, including test protocols, line data, and a summary of the results, for each applicable intermediate and final design parameter and manufacturing step, that includes, but is not limited to the test data specified in tables 1 to 22 of this paragraph for the product category as applicable. If the test data specified in the applicable table does not apply to the tobacco product, applicants must explain why the test data does not apply or how alternative test data would satisfy this requirement. Where tobacco cut size or particle size is a required design parameter for a product category or subcategory and the 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;

TABLE 2 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigarette length (mm). • Cigarette circumference or diameter (mm). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%). • Cigarette paper length (mm). • Cigarette paper base paper porosity (permeability) (CU).	• Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%). • Cigarette paper base paper porosity (permeability) (CU). • Cigarette paper band porosity or permeability (CU) or Cigarette paper band diffusivity (cm^2/s). • Filter pressure drop (mm H_2O).

TABLE 2 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGARETTES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigarette paper band porosity (permeability) (CU) [alternatively, band diffusivity (cm^2/s)] (if applicable). • Cigarette paper band width (mm). • Cigarette paper band space (mm). • 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 cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)). • Tipping paper length (mm). • Filter ventilation (%).	• 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, total denier, and filter density)). • Filter ventilation (%).

TABLE 3 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NONPORTIONED SMOKELESS TOBACCO PRODUCTS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) 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). • Portion material thickness (mm) (if applicable). • Pouch material basis weight (g/m^2) (if applicable). • Pouch material porosity (permeability) (CU or $L/m^2/s$) (if applicable). • Nicotine dissolution rate (%/min).	• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron). • Tobacco moisture (%). • Portion mass (mg). • Pouch material basis weight (g/m^2) (if applicable). • Pouch material porosity (CU) (permeability) ($L/m^2/s$). • Nicotine dissolution rate (%/min).
Nonportioned Smokeless Tobacco Products	
• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron) • Tobacco moisture (%)	• Tobacco cut size (mm or CPI) or tobacco particle size (mm or micron). • Tobacco moisture (%).

TABLE 4 TO PARAGRAPH (I)(2)(II)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO ROLLING PAPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Roll-your-own (RYO) paper length (mm). • RYO paper width (mm). • RYO mass per paper (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (permeability) (CU). • RYO paper band porosity (permeability) (CU) or [alternatively, RYO paper band diffusivity (cm^2/s)] (if applicable). • RYO paper band width (mm) (if applicable). • RYO paper band space (mm) (if applicable).	• RYO mass per paper (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper base paper porosity (permeability) (CU). • RYO paper band porosity (permeability) (CU) or [alternatively, RYO paper band diffusivity (cm^2/s)] (if applicable).

TABLE 5 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube circumference or diameter (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • Tube paper band width (mm) (if applicable). • Tube paper band space (mm) (if applicable).	• Tube mass (mg). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable).

TABLE 6 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tube mass (mg). • Tube length (mm). • Tube circumference or diameter (mm). • Tube paper length (mm). • Nonfilter tube length (mm). • Tube paper width (mm). • Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • Tube paper band width (mm) (if applicable). • Tube paper band space (mm) (if applicable). • 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 cigarette filter is unchanged (e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))). • Tipping paper length (mm). • Filter ventilation (%).	• Tube paper base paper basis weight (g/m^2). • Tube paper base paper porosity (permeability) (CU). • Tube mass (mg). • Tube paper band porosity (permeability) (CU) (if applicable) or Tube paper band diffusivity (cm^2/s) (if applicable). • 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 cigarette filter is unchanged (e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3))). • Filter ventilation (%).

TABLE 7 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (mm or CPI). • Tobacco moisture or oven volatiles (%).

TABLE 8 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO PAPER TIPS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• RYO paper tip length (mm). • RYO paper tip width (mm). • RYO paper tip mass (mg). • RYO paper base paper basis weight (g/m^2). • RYO paper porosity (permeability) (CU). • RYO paper tip ventilation (%).	• RYO paper base paper basis weight (g/m^2). • RYO paper porosity (permeability) (CU). • RYO paper tip ventilation (%).

TABLE 9 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR FILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) 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 cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper band porosity (permeability) (CU) (if applicable). • Cigar wrapper band width (mm) (if applicable). • Cigar wrapper band space (mm) (if applicable). • Cigar binder porosity (permeability) (CU). • Cigar binder band porosity (permeability) (CU) (if applicable). • Cigar binder band width (mm) (if applicable). • Cigar binder band space (mm) (if applicable). • Filter length (mm). • Filter diameter (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 cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. • Tipping paper length (mm). • Filter ventilation (%).	• Cigar mass (mg). • Puff count. • Cigar wrapper basis weight (g/m^2). • Cigar wrapper porosity (permeability) (CU). • Cigar binder porosity (permeability) (CU). • Cigar binder basis weight (g/m^2). • 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 (permeability) (CU) [alternatively, band diffusivity (cm^2/s)](if applicable). • Cigar binder band porosity (permeability) (CU) [alternatively, band diffusivity (cm^2/s)] (if applicable). • Cigar minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • 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 cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density (g/cm^3)]}. • Filter ventilation (%).

TABLE 10 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR UNFILTERED SHEET-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Cigar overall diameter (mm). • Cigar minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • Tobacco rod density (g/cm^3). • Tobacco moisture or oven volatiles (%). • Tobacco cut size (CPI or mm). • Tobacco filler mass (mg). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder porosity (permeability) (CU). • Cigar binder width (mm) • Cigar binder basis weight (g/m^2). • Cigar tip length (mm) (if applicable). • Cigar tip inner diameter (mm) (if applicable). • Cigar tip mass (mg) (if applicable). • Cigar wrapper band space (mm) (if applicable).	• 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 minimum diameter (mm) (if applicable). • Cigar maximum diameter (mm) (if applicable). • Cigar wrapper porosity (permeability) (CU). • Cigar wrapper basis weight (g/m^2). • Cigar binder basis weight (g/m^2). • Cigar binder porosity (permeability) (CU). • Cigar tip mass (mg) (if applicable). • Cigar wrapper band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable). • Cigar binder band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable).

TABLE 10 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR UNFILTERED SHEET-WRAPPED CIGARS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper band width (mm) (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 (cm2/s)] (if applicable). • Cigar binder band porosity (permeability) (CU) [alternately, band diffusivity (cm2/s)] (if applicable).	

TABLE 11 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR LEAF-WRAPPED CIGARS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar mass (mg). • Cigar length (mm). • Overall diameter (mm). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Tobacco moisture or oven volatiles (%). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%). • 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).	• Puff count. • Cigar mass (mg). • Cigar minimum diameter (mm). • Cigar maximum diameter (mm). • Cigar wrapper basis weight (g/m^2). • Cigar binder basis weight (g/m^2). • Tobacco filler mass (mg). • Tobacco rod density (g/cm^3). • Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 12 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm) • Tobacco moisture or oven volatiles (%)	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 13 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR CIGAR WRAPPERS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/cm^2).	• Cigar wrapper length (mm). • Cigar wrapper width (mm). • Cigar wrapper basis weight (g/cm^2).

TABLE 14 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Hose length (mm). • Hose materials. • Hose internal diameter (mm). • Stem length (mm). • Stem internal diameter (mm). • Base diameter (mm). • Base volume (cm^3). • Base shape.	• 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 (%).

TABLE 14 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPES—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Pressure drop (mm H_2O). • Water filter efficiency (%). • Hose air permeability (CU). • Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Number of holes. • Head volume (mm^3). • Heating source type. • Head materials.	• Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Head volume (mm^3).

TABLE 15 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 16 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE HEATING SOURCES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Heating element temperature range (°C). • Heating element mass (mg). • Heating element density (g/cm^3). • Heating element resistance (ohms) (if applicable). • Number of heating elements. • Heating element configuration. • Heating element diameter (gauge) (if applicable). • 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) temperature cut-off (°C) (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).	• Heating element temperature range (°C). • Heating element mass (mg). • Heating element density (g/cm^3). • Heating element resistance (ohms) (if applicable). • 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) temperature cut-off (°C) (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).

TABLE 17 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE FOIL

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Foil length (mm) (for square or rectangular shape foil). • Foil width (mm) (for square or rectangular shape foil). • Diameter (mm) (for circular shape foil). • Foil thickness (mm). • Number of holes. • Diameter of the holes (mm).	• Foil length (mm) (for square or rectangular shape foil). • Foil width (mm) (for square or rectangular shape foil). • Diameter (mm) (for circular shape foil). • Foil thickness (mm). • Diameter of the holes (mm).

TABLE 18 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR WATERPIPE HEAD

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Head height (mm), • Head top diameter (mm), • Head bottom diameter (mm), • Number of holes, • Head volume (mm^3), • Head materials,	• Head height (mm). • Head top diameter (mm). • Head bottom diameter (mm). • Head volume (mm^3).

TABLE 19 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPES

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Bowl chamber cover outer diameter (mm). • Bowl chamber cover inner diameter (mm). • Draught hole diameter (mm). • Screen (if applicable). • Draught hole shape. • Draught hole location. • Bowl chamber hole shape. • Bowl chamber volume (cm^3) • Airway volume (cm^3) • Stem length (mm). • Stem diameter (mm). • Shank length (mm). • Shank diameter (mm). • Draught hole dimension. • Pressure drop through air valve (mm H_2O). • Air flow through air valve (cc/min). • 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., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. • Filter pressure drop (mm H_2O). • Filter length (mm).	• Bowl chamber volume (cm^3). • Pipe pressure drop (mm H_2O). • Air flow through air valve (cc/min). • Airway volume (cm^3). • 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 cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}.

TABLE 20 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR PIPE TOBACCO

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).	• Tobacco cut size (CPI or mm). • Tobacco moisture or oven volatiles (%).

TABLE 21 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR ENDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Draw resistance (mm H_2O). • Puff count (for full tank/cartridge). • Atomizer tank/cartridge volume (mL). • Number 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).	• 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).

TABLE 21 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR ENDS—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• 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). • Airflow rate (L/min) (if applicable). • PDU Current cut-off (mA) (if applicable). • PDU Temperature cut-off (°C) (if applicable). • Inhaled aerosol temperature (°C). • Ventilation (%).	• 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). • Battery maximum charging current (mA). • Battery maximum discharging current (mA). • Battery upper limits charging voltage (V). • Inhaled aerosol temperature (°C). • Airflow rate (L/min) (if applicable). • Ventilation (%).

TABLE 22 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR E-LIQUIDS

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) 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).	• 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 23 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR HEATED TOBACCO PRODUCTS (HTP)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
• Overall Product. ○ Mass (mg). ○ Length (mm). ○ Width (mm). ○ Height (mm). ○ Diameter (mm). ○ Draw resistance (mm H_20). ○ 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 (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 (i.e., the shape and design of the heating element. If the heating element is a coil, it is the shape and arrangement of the coil. If the heating element is a novel design, provide the configuration and its design targets.).	• Overall Product. ○ Draw resistance (mm H_2O). ○ Puff count (for full tank/cartridge). ○ 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 (permeability) (CU) (if applicable). • Heating element. ○ Heating Element diameter (gauge). ○ Heating Element resistance (Ohms). ○ Heating Element temperature range (°C). • E-liquid. ○ E-liquid viscosity (at 20 °C). ○ E-liquid volume (ml). • Tobacco (if applicable). ○ Tobacco moisture (%). ○ Tobacco cut size (CPI or mm). ○ Tobacco density (g/cm^3) • Battery.

TABLE 23 TO PARAGRAPH (i)(2)(ii)—REQUIRED DESIGN PARAMETER INFORMATION FOR HEATED TOBACCO PRODUCTS (HTP)—Continued

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
○ Heating element length (mm). ○ Heating element mass (mg). ○ Heating element location. ○ Number of heating elements (e.g., coil) (dimensionless). ○ 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 (mA). ○ 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). ○ 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 cigar filter is unchanged [e.g., denier per filament (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 (%).	○ Battery voltage operating range (V). ○ Battery current operating range (mA). ○ PDU voltage operating range (V). ○ PDU current operating range (mA) PCO wattage operating range (W). ○ PDU Current cut-off (mA) (if applicable). ○ PDU temperature cut-off (°C). ○ Battery Capacity (mAh). ○ Battery Nominal Voltage (V). ○ Battery Current rating (mA). ○ 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). • 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 cigar filter is unchanged [e.g., denier per filament (DPF), total denier (g/9000m), and filter density(g/cm^3)]}. ○ Filter ventilation (%). ○ Filter pressure drop (mm H_2O).

(iii) *Function.* How the product is intended to function.

(iv) *Product pH and nicotine formulation.* The pH of the product and the formulation of nicotine in the product, if applicable, including the form (*e.g.*, unprotonated nicotine, nicotine salts) and quantity.

(v) *Fermentation process.* For smokeless tobacco products and tobacco products that contain fermented tobacco (including naturally fermented tobacco), information on the fermentation process, including the following:

(A) Description of the fermentation process;

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

(C) Any step(s) taken to reduce endogenous microbes (*e.g.*, cleaning of product contact surfaces);

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

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

(F) Duration of fermentation;

(G) Added ingredients;

(H) 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

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

(vi) *Heat treatment process.* For tobacco products that are heat treated, the application must contain the following information regarding the heat treatment process:

(A) Description of the heat treatment process;

(B) Type of heat treatment;

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

(D) Method validation data, including microbial loads (including bacteria, spores, yeast, and fungi) and TSNAs before and after heat treatment.

(vii) *Shelf life and stability information.* With the exception of applications for roll-your-own tobacco products and cigarettes that are not HTPs, the application must contain information on the stability of the tobacco product over the shelf life and including the following:

(A) The length of the shelf life, a description of how the shelf life is determined, and a description of how shelf life is indicated on the tobacco product, if applicable;

(B) 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: Microbial content data, including total aerobic microbial count and total yeast and mold count; water activity; tobacco-specific nitrosamines (TSNAs) yields (total TSNAs, N′-nitrosonor-nicotine (NNN), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) (NNK)); and preservatives content.

(C) Stability testing details for each microbial and chemical endpoint, including: The mean quantity and variance with unit of measures; the number of samples and measurement replicates for each sample; the methods used, including any deviation(s) from the methods, associated reference(s), and full validations reports for each method; 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; length of time between date of tobacco product manufacture and date(s) of testing; storage conditions of the tobacco product before it was tested; 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 full test data (including quantitative acceptance (pass/fail) criteria, complete data sets, and a summary for the results) for all stability testing performed.

(viii) *Product and packaging design risks and misuse hazards.* A review and assessment of reasonably foreseeable risks associated with the design of the tobacco product and its package that may occur during normal use of the tobacco product or during any foreseeable misuse of the product, including user error, which may cause illness, injury, or death not normally associated with the use of the tobacco product. The review and assessment must identify the measures taken to reduce or eliminate each risk associated with the design of the tobacco product and package.

(3) *Principles of operation.* The applicant must provide a full statement of the principle or principles of operation

of the tobacco product, including full narrative descriptions of:

(i) The way in which a typical consumer will use the new tobacco product, including a description of how a consumer operates the product, how long a single unit of product is expected to last (*e.g.*, total length of time of use to consume a unit, number of use sessions expected per unit), and, where applicable, how a consumer can change the product design and add or subtract ingredients;

(ii) A justification for an applicant's determination of what constitutes a single unit of product as described in the PMTA; and

(iii) Whether the product incorporates a heating source, and if so, a description of the heating source.

(4) *Product testing and analysis information.* Each analysis required in this paragraph must be performed on test samples that reflect the finished tobacco product composition and design, and must be conducted using a sufficient sample size and number of replicates to substantiate the results of the type of testing conducted. Additionally, the applicant must provide the following information:

(i) The name and location of 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;

(ii) The length of time between dates of manufacture and date(s) of testing;

(iii) The storage conditions of the tobacco product before it was tested;

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

(v) A description of method procedure, method validation information and rationale for selecting each test method, including relevant voluntary testing standards, test protocols, quantitative acceptance criteria, line data, and a summary of the results;

(vi) Reports of product formulation testing that include test protocols, quantitative acceptance criteria, line data, and a summary of the results, for each applicable design parameter; and

(vii) 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.

(j) *Manufacturing.* The application must contain a full description of the methods used in, and the facilities and controls used for, the design (including design validation and design verification, to assess whether the tobacco product, as manufactured, performs in accordance with design specifications), manufacture, packing, and storage of the tobacco product in sufficient detail to demonstrate whether the product meets manufacturing specifications, can be manufactured in a manner consistent with the information submitted in the application, and conforms to the requirements of any regulations issued under section 906(e) of the Federal Food, Drug, and Cosmetic Act, including:

(1) A list of all manufacturing, packaging, storage, and control facilities for the product, including the facility name, address, and FEI number, if applicable, and a contact name and telephone number for a representative from each facility;

(2) A narrative description, accompanied by a list and summary, of all standard operating procedures (SOPs) and examples of relevant forms and records for the following categories of information for all manufacturing, design controls, packing, and storage for the tobacco product:

(i) Manufacturing and production process activities at each establishment, including a description of each establishment, all production steps, and process controls, process specifications with relevant acceptance criteria, and monitoring and acceptance activities;

(ii) Managerial oversight and employee training related to the manufacture, processing, packing, and installation of the tobacco product, as applicable;

(iii) Monitoring procedures and manufacturing controls for product design, product characteristics, and changes in products, specifications, methods, processes, or procedures, including a hazard analysis that details the correlation of the product design attributes with public health risk, as

well as any mitigation strategies implemented;

(iv) Activities related to identifying and monitoring suppliers and the products supplied (including, for example, purchase controls and product acceptance activities);

(v) Handling of complaints, nonconforming products and processes, and corrective and preventative actions;

(vi) Testing procedures carried out before the product is released to market, including:

(A) A list and summary of any standards used for all testing methods;

(B) Validation and verification activities for all test methods used to ensure that the tobacco product meets specifications;

(C) Documentation of accreditation information for all testing laboratories;

(D) Complete description of smoking or aerosol-generating regimes used for analytical testing, if any; and

(E) Tobacco product specifications (including any physical, chemical, and biological specifications) and acceptance criteria for those specifications;

(F) Reports of release testing performed on finished products to demonstrate conformity with established specifications, including test protocols, line data, and a summary of the results for each applicable testing.

(k) *Health risk investigations*—(1) *Study types.* The application must contain full reports of all information, both favorable and unfavorable, published or known to, or which should reasonably be known to, the applicant concerning investigations, including nonclinical and human subject studies regarding the following topics. If no substantive information exists regarding the topics specified in §1114.27(b)(1)(ii), including information from published literature or that may be bridged from an investigation of another tobacco product, an applicant may need to conduct its own investigation(s) to ensure substantive information is included in the PMTA to meet the application filing requirements.

(i) *Health risks of the product.* The potential health risks of the tobacco product to users and nonusers, including potential exposures and information regarding risks to youth, young adults, and other relevant vulnerable populations, and whether the product may present different risks than other tobacco products, including:

(A) The health effects of the constituents, including HPHCs, at the quantitative levels delivered to both users and nonusers under the range of conditions under which the product might be used;

(B) The toxicological profile of the new tobacco product related to the route of administration, including the genotoxicity, carcinogenicity, reproductive toxicity, immunotoxicity, acute toxicity, and repeat dose (chronic) toxicity of the new tobacco product relative to other tobacco products. The toxicological profile also includes information on the toxicity of the ingredients, additives, and HPHCs, relative to the route of administration and the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product, including studies which discuss the toxicological effects of any leachables and extractables that can appear from the container closure system and the ingredient mixture, such as additive or synergistic effects;

(C) The pharmacological profile of the new tobacco product, including the pharmacokinetics, pharamacodynamics, metabolism, and elimination profile, of any of the ingredients, additives, and HPHCs for the range of potential levels of exposure resulting from the use of, or exposure to, the new tobacco product relative to other tobacco products. The applicant must specify whether the studies were conducted in vitro, in vivo, ex vivo, or in silico; and

(D) The health risks of the tobacco product compared to other tobacco products on the market, never using tobacco products, quitting tobacco product use, and using the tobacco product in conjunction with other tobacco products.

(ii) *Impacts on tobacco use behavior of tobacco product users.* How the product and its label, labeling, and advertising, to the extent that advertising has been studied, will affect the tobacco use behavior of tobacco product users, specifically considering youth, young

adults, and other relevant vulnerable populations, including:

(A) The abuse liability of the tobacco product;

(B) How users actually use the product, including use topography, product use frequency, use trends over time, and how such use affects the health risks of the product to individual users;

(C) The likelihood that users will use the product in conjunction with other tobacco products;

(D) The likelihood that current tobacco product users will start using the product;

(E) The likelihood that current tobacco users who adopt the product will switch to or switch back to other tobacco products that may present increased risks to individual health; and

(F) The likelihood that current tobacco users who may have otherwise quit using tobacco products will instead start or continue to use the product.

(iii) *Impacts on tobacco use initiation by nonusers, including youth, young adults, and other relevant vulnerable populations.* The impact of the tobacco product and its label, labeling, or advertising, to the extent that advertising has been studied, on tobacco use initiation by nonusers, including:

(A) The likelihood that consumers who have never used tobacco products, particularly youth, young adults, and other relevant vulnerable populations, will initiate use of the tobacco product;

(B) The likelihood that nonusers of tobacco products who adopt the tobacco product will switch to other tobacco products that may present higher levels of individual health risk; and

(C) The likelihood that former users of tobacco products will re-initiate use with the tobacco product.

(iv) *Perceptions and use intentions.* The impact of the product and its label, labeling, and advertising, to the extent that advertising has been studied, on individuals:

(A) Perception of the product;

(B) Use intentions; and

(C) Ability to understand the labeling and instructions for use and use the product in accordance with those instructions.

(v) *Human factors.* The impact of human factors on product risk, including discussion of use conditions, use environments, use related hazards, estimated use error risk, potential unintended uses, risk controls to ensure that harms and unintended consequences are minimized, and adverse experiences related to such uses.

(2) *Literature search.* The applicant must conduct a literature search for each type of information described in paragraph (k)(1) of this section, and the application must contain a description of the literature search performed, including the databases searched and the date searched, search terms, reasons for inclusion or exclusion of documents, and the strategy for study quality assessment. The application must also contain a bibliography of all published studies and articles referenced in the application. If a literature search was performed and resulted in no information found, the application must contain a statement to that effect.

(3) *Study reports.* The full report of each study included in the application must describe the specific product studied and include the following items, where applicable and to the extent reasonably available. For applicable items not contained in the full report of an investigation, the applicant must contain a description of the actions taken to obtain the information and why the document is not reasonably available.

(i) Full copies of any published articles and other reference materials;

(ii) Documentation of all actions taken to ensure the reliability of the study. For all studies, to the extent reasonably available or obtainable, the application must contain a certification that investigators do not have, or documentation fully disclosing, any financial conflicts of interest, such as the financial arrangements specified in the Financial Disclosure by Clinical Investigators regulation in part 54 of this chapter. Additionally, for nonclinical laboratory studies, the application must contain, for each study, documentation of all actions taken to ensure the reliability of the study, *e.g.*, documentation of whether the study was conducted in accordance with good laboratory practices, such as those specified in part 58 of this chapter;

(iii) Copies of all versions of protocols and amendments that were used in the study;

(iv) Copies of all versions of investigator instructions, if any were produced in addition to the protocol;

(v) The statistical analysis plan, including a detailed description of the statistical analyses used (including all variables, confounders, and subgroup analyses), the scientific rationale for the choice of sample sizes, and any amendments to the plan;

(vi) Line data, including data definition files that include the names of the variables, codes, and formats in each dataset, and copies of programs and any necessary macro-programs used to create derived datasets, and the results included in the study reports;

(vii) A list of sites and clinical investigators that conducted the study, including contact information and physical address(es);

(viii) The location of all source data. If the site where the study was conducted has not maintained all of the source data, indicate where the data are located;

(ix) The format of the records and data (*e.g.*, electronic or hard copy);

(x) A list of all sites that had early termination and the reason for early termination, if applicable;

(xi) A list of contractors who participated in the study, the role of each contractor, and the initiation and termination dates of the participation of each contractor;

(xii) A signed full report of all findings;

(xiii) For human subject studies:

(A) All versions of study materials (*e.g.*, consent forms, questionnaires, stimuli) used;

(B) All versions of case report forms used; and

(C) Individual case report forms related to participant deaths, other serious and unexpected adverse experiences, withdrawals, and participant discontinuation where the study participant was exposed to the tobacco product that is the subject of the PMTA or similar products; and

(xiv) For tobacco product perception and use intention studies that use advertising as stimuli, a statement describing whether the advertising used is representative of advertising that the applicant intends to use in marketing the product. If the advertising is not representative of the advertising an applicant intends to use in marketing the product, the applicant must describe whether the study results are still relevant to the likely impact of the advertising on tobacco product perceptions and use intentions.

(*l*) *The effect on the population as a whole.* The application must contain an analysis and discussion of how the data and information contained in the application establish that permitting the tobacco product to be marketed would be appropriate for the protection of public health determined with respect to the population as a whole, including users and nonusers of the tobacco product. The analysis and discussion must integrate all of the information in the application regarding the product and its likely effects on health, and tobacco use behavior, including tobacco use cessation and initiation, to provide an overall assessment of the likely effect that the marketing of the tobacco product may have on overall tobacco-related morbidity and mortality.

(m) *Certification statement.* The application must contain the following certification, with the appropriate information inserted (as indicated by parenthetical italicized text), signed by an authorized representative of the applicant:

''I (*name of responsible official*) on behalf of the applicant, (*applicant name*), hereby certify that the applicant will maintain all records to substantiate the accuracy of this application for the period of time required in 21 CFR 1114.45 and ensure that such records remain readily available to 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.''

§ 1114.9 Amendments.

(a) *General.* FDA may request, or an applicant may submit on its own initiative, an amendment to a PMTA containing information that is necessary for FDA complete the review of a pending PMTA. An amendment must include the appropriate form and specify the STN assigned to the original submission and, if submitted other than at FDA's request, the reason for submitting the amendment. An amendment must also include the certification statement set forth in § 1114.7(m), with the appropriate information inserted, and signed by an authorized representative of the applicant.

(b) *Review of an amendment.* Submission of an amendment may affect the timing of review of an amended submission as follows:

(1) If the amendment is a major amendment (*e.g.*, an amendment that contains significant new data from a previously unreported study, detailed new analyses of previously submitted data, or substantial new manufacturing information), FDA will restart the 180-day review period after receipt of the amendment.

(2) If FDA requests a minor amendment (*i.e.*, an amendment that is not a major amendment) and receives a written response submitting the requested amendment, FDA may pause the review period for the number of days elapsed between the date of the request and the date that FDA receives the written response.

(c) *Failure to respond to amendment request.* If FDA requests an amendment and the applicant does not respond within the time period specified in FDA's request, FDA may consider the applicant to have submitted a request to voluntarily withdraw the pending PMTA under § 1114.11 and issue an acknowledgment letter notifying the applicant of the withdrawal.

(d) *No amendment to closed or withdrawn application.* An applicant may not amend an application after FDA has closed the application through an action under § 1114.29 or it has been withdrawn under § 1114.11.

§ 1114.11 Withdrawal by applicant.

(a) An applicant may at any time make a written request using the appropriate form to withdraw a PMTA that FDA has not acted on as described in § 1114.29. The withdrawal request must state:

(1) Whether the withdrawal is due to a health concern related to the tobacco product and, if so, a description of those concerns, including the extent, duration, and frequency of the health effects, and what gave rise to the concerns, such as reports of adverse experiences;

(2) The application STN; and

(3) The name(s) of the new tobacco product that is the subject of the application.

(b) An application will be considered withdrawn when FDA issues an acknowledgement letter stating that the application has been withdrawn.

(c) The application is an Agency record, even if withdrawn. FDA will retain the withdrawn application under Federal Agency records schedules. The availability of the withdrawn application will be subject to FDA's public information regulation in Part 20 of this chapter.

§ 1114.13 Change in ownership of an application.

An applicant may transfer ownership of a PMTA. At or before the time of transfer, the new owner and the former owner must submit information to FDA using the appropriate form as follows:

(a) The new and former owner must sign and submit a notice to FDA stating that all of the former applicant's rights and responsibilities relating to the PMTA have been transferred to the new owner. This notice must identify the name and address of the new owner and the PMTA transferred by tobacco product name(s) and STN.

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

(1) The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application and marketing granted order, if applicable;

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

(3) Either a statement that the new owner has a complete copy of the application, including all amendments, the

marketing granted order (if applicable), and any records that are required to be kept under §1114.45, or a request for a copy of the application, including all amendments, and the modified risk order (if applicable) from FDA's files in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the application to the new owner 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 tobacco product since the application, including amendments (if any), was submitted to FDA.

§1114.15 Supplemental applications.

(a) *Supplemental PMTA submission.* Applicants that have received a marketing granted order for a tobacco product may, as an alternative format of submitting an application that meets the content requirements of §1114.7, submit a supplemental PMTA to seek marketing authorization for modifications to such product, which result in a new tobacco product under section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act. Supplemental PMTAs must include new information concerning modifications that create the new tobacco product but allow the applicant to satisfy the remaining application requirements by cross-referencing applicable content from the previously submitted PMTA for the original tobacco product. Applicants may submit supplemental PMTAs only for modifications that require the submission of limited new information or where specified in a rule under section 907 of the FD&C Act. Except as permitted in a rule under section 907 of the Federal Food, Drug, and Cosmetic Act, an applicant may not submit a supplemental PMTA where:

(1) Modifications to the product that result in the new tobacco product require the submission of new information or revisions to the PMTA for the original product to the extent that reviewing a supplemental application for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under §1114.7 would better facilitate review.

(2) The marketing granted order for the original tobacco product has been withdrawn; or

(3) The marketing granted order for the original tobacco product has been temporarily suspended or is subject to temporary suspension or withdrawal proceedings by FDA, except where authorized in writing by FDA.

(b) *Required format.* The supplemental PMTA must comply with format requirements of §1114.7(b), except that an applicant must include certain content in a supplemental PMTA by cross-referencing a PMTA, or, where applicable, a supplemental PMTA, for an original tobacco product that is owned by that applicant, and may include other content by cross-referencing a tobacco product master file and postmarket reports for the original tobacco product. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The supplemental PMTA must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must contain the full text of all the information described in the following sections:

(i) General information that identifies the submission as a supplemental PMTA (as described in §1114.7(c));

(ii) New product information (as described in paragraph (d) of this section);

(iii) Statement of compliance with 21 CFR part 25 (as described in §1114.7(g));

(iv) Labeling (as described in §1114.7(f)) if the labeling is not identical to the labeling submitted in the PMTA or postmarket reports for the original product;

(v) Postmarket information (as described in paragraph (e) of this section); and

(vi) Certification statement (as described in paragraph (f) of this section);

(2) The application must include the following sections by cross-reference to the PMTA for the original tobacco

product and contain any additional information that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f)) if the labeling is identical to the labeling that was submitted in the PMTA or postmarket reports for the original tobacco product;

(iv) Summary of all research findings (as described in § 1114.7(h));

(v) Product formulation (as described in § 1114.7(i));

(vi) Manufacturing (as described in § 1114.7(j)); and

(vii) Health risk investigations (as described in § 1114.7(k)).

(d) *New product information.* The application must contain a section that includes:

(1) Full descriptions of each modification to the product and comparisons to the original product version described in the previously authorized PMTA;

(2) A statement as to whether the new tobacco product, if it receives a marketing granted order, will replace the original tobacco product, will be a line extension of the original tobacco product, or will be introduced as an additional product by the same manufacturer;

(3) All data and information relating to each modification to the product that would be required in an application under § 1114.7; and

(4) A concluding summary of how the new tobacco product meets the requirements to receive a marketing granted order, including how the data and information contained in both the supplemental PMTA and cross-referenced from the previously authorized PMTA constitute valid scientific evidence and establishes that the PMTA meets the requirements of section 910(c) of the Federal Food, Drug, and Cosmetic Act to receive a marketing granted order, including that permitting the new tobacco product to be marketed would be appropriate for the protection of the public health determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product.

(e) *Postmarket reports.* (1) If an applicant has submitted postmarket reports for the original tobacco product, the applicant must include all such reports in the application by cross-reference.

(2) If an applicant is required to, but has not yet submitted a postmarket report, the applicant must submit a report as part of its application that contains all of the information for the original tobacco product that would otherwise be required in a report under § 1114.41 covering the period of time from when it received a marketing granted order for the original tobacco product to when it submits the supplemental PMTA.

(f) *Certification statement.* The application must contain the following certification, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that (*new tobacco product name*) has a different (*describe each modification to the product*) than (*name of original tobacco product*) described in (*STN of the PMTA for the original product*) but is otherwise identical to (*name(s) of original tobacco product*). I certify that (*name of applicant*) understands this means there is no other modification to the materials, ingredients, design, composition, heating source, or any other feature of the original tobacco product. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this application and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, 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.''

§ 1114.17 Resubmissions.

(a) *General.* An applicant may, as an alternative format of submitting an application that meets the content requirements of § 1114.7 or 1114.15 (if applicable), submit a resubmission to address deficiencies set forth in a marketing denial order. The resubmission must contain new information necessary to address application deficiencies and cross-reference applicable content from the PMTA that received the marketing denial order. An applicant may utilize the resubmission format for the same tobacco product for which FDA issued a marketing denial order or a new tobacco product that results from modifications to the product necessary to address the deficiencies described in a marketing denial order. An applicant may not submit a resubmission when:

(1) It incorporates new information or revisions to the PMTA for the original product to the extent that reviewing a resubmission for the new tobacco product would be confusing, cumbersome, or otherwise inefficient and submitting a standard PMTA under § 1114.7 would better facilitate review; or

(2) The marketing denial order states that the applicant may not submit a resubmission.

(b) *Required format.* The resubmission must comply with format requirements of § 1114.7(b), except that an applicant must include content in the resubmission by cross-referencing the PMTA, or, where applicable, supplemental PMTA, that received the marketing denial order. An applicant may also include content in a resubmission by cross-reference to a TPMF. FDA will not consider content included by cross-reference to other sources of information outside of the submission.

(c) *Required content.* The resubmission must provide sufficient information for FDA to determine whether any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply to the application.

(1) The application must include the full text of the information described in the following paragraphs:

(i) General information that identifies the submission as a resubmission (as described in paragraph § 1114.7(c));

(ii) Response to deficiencies (as described in paragraph (d) of this section); and

(iii) Certification statement (as described in paragraph (e) of this section).

(2) The application must include the following sections from the PMTA that received a marketing denial order by cross-reference to the PMTA and contain all additional information, in full text or by reference to a tobacco product master file, that is necessary to supplement or update the cross-referenced information:

(i) Descriptive information (as described in § 1114.7(d));

(ii) Product samples (as described in § 1114.7(e));

(iii) Labeling (as described in § 1114.7(f));

(iv) Statement of compliance with 21 CFR part 25 (as described in § 1114.7(g));

(v) Summary of all research findings (as described in § 1114.7(h));

(vi) Product formulation (as described in § 1114.7(i));

(vii) Manufacturing (as described in § 1114.7(j)); and

(viii) Health risk investigations (as described in § 1114.7(k)).

(d) *Response to deficiencies.* (1) The application must include a section that lists and provides a separate response to each deficiency described by FDA in the original marketing denial order, including all data and information necessary to complete each response, and that also addresses any applicant-identified deficiencies.

(2) Where an applicant modifies the product in a way that would result in a new tobacco product under section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act in order to address the deficiencies, the application must also include:

(i) A full description of each modification to the product and comparisons of that change to the original version of the product described in the previously submitted PMTA; and

(ii) All data and information relating to each modification to the product that would be required in an application under § 1114.7.

(e) *Certification statement.* The application must contain one of the two following certifications that corresponds to the application, with the appropriate information inserted as indicated by parenthetical italicized text, signed by an authorized representative of the applicant.

(1) *Same tobacco product certification.* An application for the same tobacco product must contain the following certification:

''I, (*name of responsible official),* on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the marketing denial order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein is identical to the product described in the previously submitted PMTA. I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design, composition, heating source, or any other feature. I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company'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) *Different tobacco product certification.* An application for a different tobacco product than the original tobacco product that results from changes necessary to address the deficiencies must contain the following certification:

''I, (*name of responsible official*), on behalf of (*name of applicant*), certify that this submission for (*new tobacco product name(s)*) responds to all deficiencies outlined in the marketing denial order issued in response to (*STN of the previously submitted PMTA*) and the new tobacco product described herein has a different (*describe each modification to the product*) than (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*) but is otherwise identical to (*name(s) of original tobacco product*) described in (*STN of the previously submitted PMTA*). I certify that (*name of applicant*) understands this means there is no modification to the materials, ingredients, design features, heating source, or any other feature of the original tobacco product, except for the (*describe each modification to the tobacco product*). I also certify that (*name of applicant*) will maintain all records that substantiate the accuracy of this statement, and ensure that such records remain readily available to FDA upon request for the period of time required in 21 CFR 1114.45. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company'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.''

Subpart C—FDA Review

§ 1114.25 Communication between FDA and applicants.

During the course of reviewing an application, FDA may communicate with an applicant about relevant matters, including scientific, medical, and procedural issues that arise during the review process and inspections. These communications may take the form of telephone conversations, letters, electronic communications, or meetings, and will be documented in the administrative file in accordance with § 10.65 of this chapter.

§ 1114.27 Review procedure.

(a) *Acceptance review.* (1) After an applicant submits a PMTA, FDA will perform an initial review of the PMTA to determine whether it may be accepted for further review. FDA may refuse to accept an application that:

(i) Does not comply with the applicable format requirements in § 1114.7(b), § 1114.15, or § 1114.17 (as applicable);

(ii) Is not administratively complete because it does not appear to contain the information required by § 1114.7 (excluding product samples), § 1114.15 or § 1114.17, as applicable;

(iii) Does not pertain to a tobacco product subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (as required by § 1105.10 of this chapter); or

(iv) FDA can otherwise refuse to accept under § 1105.10.

(2) If FDA accepts an application for further review, FDA will issue an acknowledgement letter to the applicant that specifies the PMTA STN. If FDA determines that it will require product samples as part of the PMTA, it will send instructions on how and where to submit product samples, as described in § 1114.7(e) of this chapter.

(3) If FDA refuses to accept an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from accepting the application.

(b) *Filing review.* (1) After accepting a PMTA, FDA will make a threshold determination of whether the application contains sufficient information to permit a substantive review. FDA may refuse to file a PMTA if any of the following applies:

(i) The PMTA does not contain sufficient information required by section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act and by § 1114.7, § 1114.15, or § 1114.17, as applicable, to permit a substantive review of the application;

(ii) The application does not contain any substantive information, including information from published literature or bridged from an investigation of another tobacco product, regarding each of the following topics.

(A) The health risks of the new tobacco product as described in either § 1114.7(k)(1)(i)(A), (B), or (C));

(B) The health risks of the new tobacco product compared to the health risks generally presented by products in the same product category as well as products in at least one different category that are used by the consumers an applicant expects will use its new tobacco product (as described in a portion of § 1114.7(k)(1)(i)(D)).

(C) The abuse liability of the new tobacco product (as set forth in § 1114.7(k)(1)(ii)(A));

(D) How consumers would be expected to actually use the product, such as use frequency, use trends over time, and how such use affects the health risks of the product to individual users (as described in § 1114.7(k)(1)(ii)(B));

(E) The potential impact that the marketing of the new tobacco product would have on the likelihood that current tobacco product users would change their tobacco product use behavior, such as starting to using the new tobacco product, using the product in conjunction with other tobacco products, or, after using the product, switching to or switch back to other tobacco products that may present increased risks to individual health (*i.e.*, any of the information set forth in either § 1114.7(k)(1)(ii)(C), (D), (E), or (F));

(F) The impact of the tobacco product and its label, labeling, or advertising, to the extent that advertising has been studied, on tobacco product use behavior of current nonusers of tobacco products (*i.e.*, any of the information described in § 1114.7(k)(1)(iii));

(G) The impact of the product and its label, labeling, or advertising, to the extent that advertising has been studied, on individuals' perception of the product and their use intentions (*i.e.*, any of the information described in § 1114.7(k)(1)(iv)); and

(H) The ways in which human factors can affect the health risks of the new tobacco product (*i.e.*, any of the information described in § 1114.7(k)(1)(v));

(iii) The PMTA contains a false statement of material fact;

(iv) The PMTA is a supplemental PMTA that does not comply with § 1114.15; or

(v) The PMTA is a resubmission that does not comply with § 1114.17.

(2) If FDA refuses to file an application, FDA will issue a letter to the applicant identifying the deficiencies, where practicable, that prevented FDA from filing the application.

(3) If FDA files an application, FDA will issue a filing letter to the applicant.

(c) *Application review.* (1) Except as described in this paragraph and § 1114.9(b), within 180 days of receipt of an application described in section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act meeting the filing requirements set out in 1114.27(b), FDA will complete its review of the PMTA and act on the application.

(2) FDA will begin substantive review of the application after it is filed under paragraph (b) of this section. FDA may communicate with the applicant as set

forth under §1114.25 to seek additional or clarifying information.

(3) FDA may refer the PMTA or portions of the PMTA, upon its own initiative or applicant request, to TPSAC for reference and for the submission of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(4) FDA may conduct inspections of the applicant's manufacturing sites, and sites and entities involved with clinical and nonclinical research (including third parties and contract research organizations) to support FDA's review of the PMTA. Where an applicant prevents FDA from scheduling and conducting inspections that are necessary for FDA to complete its review of the PMTA in a timely manner, FDA may pause the 180-day review period for the number of days necessary to complete the inspection.

(5) FDA may defer review of a PMTA for a new product that, if introduced or delivered for introduction into interstate commerce, would be adulterated or misbranded due to the manufacturer or importer's failure to comply with user fee payment and reporting requirements under part 1150.

§ 1114.29 FDA action on an application.

After receipt of an application, FDA will:

(a) Refuse to accept the application as described in §1114.27(a);

(b) Issue a letter administratively closing the application;

(c) Issue a letter canceling the application if FDA finds that it mistakenly accepted the application or that the application was submitted in error;

(d) Refuse to file the application as described in §1114.27(b);

(e) Issue a marketing granted order as described in §1114.31; or

(f) Issue a marketing denial order as described in §1114.33.

§ 1114.31 Issuance of a marketing granted order.

(a) FDA will issue a marketing granted order if it finds that none of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply. A marketing granted order becomes effective on the date it is issued.

(b) FDA may include, as part of the marketing granted order:

(1) Restrictions on the sale and distribution of the product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, to the extent that it would be authorized to impose such restrictions under a regulation issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act;

(2) Any restrictions on the sales, distribution, advertising, and promotion of the new tobacco product that the applicant proposed to be included as part of a marketing granted order under section 910(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act to support a finding by FDA that permitting the product to be marketed would be appropriate for the protection of the public health; and

(3) Requirements to establish and maintain records, and submit postmarket reports under section 910(f) of the Federal Food, Drug and Cosmetic Act in addition to those described in §1114.41, including but not limited to information such as labeling, advertising, marketing, promotional materials, or marketing plans not previously submitted to FDA.

§ 1114.33 Issuance of a marketing denial order.

(a) *Issuance.* FDA will issue a marketing denial order if:

(1) Upon the basis of the information submitted as part of the application and any other information before FDA with respect to the new tobacco product, FDA finds that any of the grounds for denial listed in section 910(c)(2) of the Federal Food, Drug, and Cosmetic Act apply;

(2) The applicant does not permit an authorized FDA employee, at a reasonable time and in a reasonable manner, an opportunity to:

(i) Inspect the facilities and controls described in the application; or

(ii) Have access to, copy, and verify all records pertinent to the application,which results in FDA finding that one or more of the grounds for denial

specified in section 910(c)(2) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Description of deficiencies.* The marketing denial order will, where practicable, identify measures to remove the application from deniable form.

§ 1114.35 Withdrawal of a marketing granted order.

(a) *Grounds for withdrawal.* FDA will withdraw a marketing granted order for a new tobacco product issued under this part if FDA determines that:

(1) Any of the grounds for withdrawal under section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act apply; or

(2) Any postmarket requirement imposed by the marketing granted order or by this part has not been met, which results in FDA finding that one or more of the grounds for withdrawal specified in section 910(d)(1) of the Federal Food, Drug and Cosmetic Act apply.

(b) *Advice and other information.* (1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw a marketing granted order.

(2) FDA may use information other than that submitted by the applicant in deciding whether to withdraw a marketing granted order.

(c) *Informal hearing.* Prior to withdrawing a marketing granted order, FDA will offer the holder of the marketing granted order an opportunity for an informal hearing under part 16 of this chapter.

(d) *Order issuance.* If the applicant does not request a hearing or, if after the part 16 hearing is held, the Agency decides to proceed with the withdrawal, FDA will issue to the holder of the marketing granted order an order withdrawing the marketing granted order for the new tobacco product.

(e) *Public notice.* FDA will give the public notice of an order withdrawing a marketing granted order for a tobacco product and will announce the basis of the withdrawal.

§ 1114.37 Temporary suspension of a marketing granted order.

(a) FDA will temporarily suspend a marketing granted order if FDA determines that there is a reasonable probability that the continued distribution of such tobacco product would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market.

(b) Before temporarily suspending a marketing granted order of a tobacco product, FDA will offer the holder of the marketing granted order an opportunity for an informal hearing under part 16 of this chapter.

(c) If, after offering the holder of the marketing granted order an opportunity for a part 16 hearing, the Agency decides to proceed with the temporary suspension, FDA will issue an order temporarily suspending the marketing granted order for a tobacco product.

(d) After issuing an order temporarily suspending the marketing granted order, FDA will proceed expeditiously to withdraw the marketing granted order for the tobacco product.

Subpart D—Postmarket Requirements

§ 1114.39 Postmarket changes.

A marketing granted order authorizes the marketing of a new tobacco product in accordance with the terms of the order. Prior to the introduction or delivery for introduction into interstate commerce of a new tobacco product that results from modification(s) to the product, an applicant must submit a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and obtain a marketing granted order for the new tobacco product, unless the new tobacco product can be legally marketed through another premarket pathway.

§ 1114.41 Reporting requirements.

(a) *Required reports.* Each applicant that receives a marketing granted order must submit to FDA all information required by the terms of the marketing granted order and by this section as described below. Each

postmarket report must be well-organized, legible, and written in English. Documents that have been translated from another language into English (*e.g.*, original study documents 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.

(1) *Periodic reports.* Each applicant must submit a periodic report to the Center for Tobacco Products (CTP) within 60 calendar days of the reporting dates specified in the applicant's marketing granted order for the life of the order and as may be required for the submission of a supplemental PMTA under §1114.15. The report must include the following:

(i) A cover letter that contains the PMTA STN, tobacco product name(s) (including the original name described in the PMTA if different), company name, date of report, and reporting period;

(ii) A description of all changes made to the manufacturing, facilities, or controls during the reporting period, including:

(A) A comparison of each change to what was described in the PMTA;

(B) The rationale for making each change and, if any, a listing of any associated changes; and

(C) The basis for concluding that each change does not result in a new tobacco product that is outside the scope of the marketing granted order and will not result in a finding that the marketing granted order must be withdrawn or temporarily suspended under section 910(d) of the Federal Food, Drug, and Cosmetic Act;

(iii) An inventory of ongoing and completed studies about the tobacco product conducted by, or on behalf of, the applicant that are within the scope of §1114.7(k) and that have not been previously reported;

(iv) Full reports of information published or known to, or which should be reasonably known to, the applicant concerning scientific investigations and literature about the tobacco product that have not been previously reported, including significant findings from publications not previously reported;

(v) A summary and analysis of all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or that the applicant is aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco product, and a summary of any changes in the health risks, including the nature and frequency of the adverse experience, and potential risk factors;

(vi) A summary of sales and distribution of the tobacco product for the reporting period, to the extent that the applicant collects or receives such data, including:

(A) Total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the product is sold;

(B) The Universal Product Code that corresponds to the product(s) identified in the PMTA; and

(C) Demographic characteristics of product(s) purchasers, such as age, gender, race or ethnicity, geographic region, and tobacco use status;

(vii) A summary of the implementation and effectiveness of policies and procedures regarding verification of the age and identity of purchasers of the product; and

(viii) A summary of all formative consumer research studies conducted (if any), among any audiences, in the formation of new labeling, advertising, marketing, or promotional materials, not previously submitted, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions and behaviors toward using the products, and including the findings or these studies and copies of the stimuli used in testing;

(xi) A summary of all consumer evaluation research studies conducted (if any), among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing, or promotional materials

and shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing;

(xii) A summary of the creation and dissemination of the products' labeling, advertising, marketing, and promotional materials (if any), including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities;

(xiii) Specimens of all labeling and descriptions of all labeling changes that have not been previously submitted under section 905(i) of the Federal Food, Drug, and Cosmetic Act, including the date the labeling was first disseminated and the date when dissemination was completely terminated;

(xiv) Full color copies of all advertising for the tobacco product that has not been previously submitted, and the original date the materials were first disseminated and the date when their dissemination was completely terminated;

(xv) A description of the implementation of all advertising and marketing plans, not previously submitted to FDA, by channel and by product, including strategic creative briefs and paid media plans, and the dollar amount(s) and flighting of such plans, by channel and by product, including a description of any of the following activities that an applicant may have engaged in:

(A) Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;

(B) Targeting of specific group(s) by age-range(s), including young adults, ages 21 to 24, and other demographic or psychographic characteristics that reflect the intended target audience, including the source of such data;

(C) With respect to individuals below the minimum age of sale, actions taken to restrict access to the products and exposure to the products' labeling, advertising, marketing, or promotion, or other consumer-directed activities;

(D) Use of owned, earned, shared, or paid media to create labeling for, advertise, market, or promote the product;

(E) Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, or promote the product;

(F) Consumer engagements conducted by the applicant, on its behalf, or at its direction, including events at which the products were demonstrated and how access was restricted to individuals at or above the minimum age of sale;

(G) Use of public-relations or other communications outreach to create labeling for, advertise, market, or promote the products;

(xvi) A summary of media tracking and optimization, by channel, by product, and by audience demographics (*e.g.*, age, gender, race/ethnicity, geographic region), including a summary of any real-time digital media monitoring and including a summary of implementation of any corrective and preventive measures to identify, correct, and prevent delivery of advertising to individuals below the minimum age of sale, not previously submitted;

(xvii) An analysis of the actual delivery of advertising impressions, by channel, by product, and by audience demographics, that have not been previously submitted, and verified against post-launch delivery-verification reports submitted to the applicant from an accredited source, where applicable;

(xviii) Additional information required to be reported under the terms of a marketing granted order (if applicable); and

(xix) An overall assessment of how the tobacco product continues to be appropriate for the protection of the public health.

(2) *Serious and unexpected adverse experience reporting.* The applicant must report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware to CTP's Office of Science through the Health and Human Services' Safety Reporting Portal or in

another manner designated by FDA (if applicable) within 15 calendar days after the report is received by the applicant.

(b) *FDA review of postmarket reports.* (1) As part of its review of a postmarket report, FDA may require the applicant to submit additional information to enable it to determine whether a change results in a new tobacco product, or to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order.

(2) FDA may notify an applicant that FDA has determined that a change described in a periodic report made under this section results in a new tobacco product outside the scope of the marketing granted order, requiring the submission of a new PMTA under § 1114.7 or a supplemental PMTA under § 1114.15 and issuance of a marketing granted order if the applicant seeks to market the new tobacco product, unless the new tobacco product can be legally marketed through a different premarket pathway.

Subpart E—Miscellaneous

§ 1114.45 Record retention.

(a) *Record retention by the applicant.* (1) Each applicant that receives a marketing granted order must maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request (including where records are maintained by a third party on an applicant's behalf). These records include, but are not limited to:

(i) All documents submitted to FDA as part of an application, periodic postmarket reports, and adverse experience reports;

(ii) All documentation demonstrating whether each:

(A) Nonclinical laboratory study was conducted in accordance with good laboratory practices that support the reliability of the results, such as the records described in part 58 of this chapter; and

(B) Clinical investigator has any financial conflicts of interest that may be a source of bias, such as the documentation described in part 54 of this chapter;

(iii) All other documents generated during the course of a study necessary to substantiate the study results, including:

(A) Communications related to the investigation between the investigator and the sponsor, the monitor, or FDA; and

(B) All source data for human subject and nonclinical investigations included in the application and postmarket reports, including records of each study subject's case history and exposure to tobacco products used in the investigation, including case report forms, progress notes, hospital records, clinical charts, X-rays, lab reports, and subject diaries; and

(iv) A list of each complaint, and a summary and analysis of all complaints, associated with the tobacco product reported to the applicant;

(2) These 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.*, original study documents 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.

(3) All records must be retained as follows:

(i) Records related to and including the PMTA must be retained for a period of at least 4 years from the date that the marketing granted order is issued.

(ii) Records related to postmarket reports, including both periodic and adverse experience reports, must be retained for a period of at least 4 years from the date the report was submitted to FDA or until FDA inspects the records, whichever occurs sooner.

(b) *Record retention by FDA.* FDA will retain information submitted to it in accordance with Federal Agency Records schedules and will provide a copy to persons to whom such information may legally be disclosed on request under the fee schedule in FDA's public information regulations in §20.45 of this chapter.

§ 1114.47 Confidentiality.

(a) *General.* FDA will determine the public availability of any part of an application and other content related to such an application, including all data and information submitted with or incorporated by reference in the application, 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 part:

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

(i) The applicant has publicly disclosed or acknowledged (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 an application to FDA; or

(ii) FDA refers the application to TPSAC.

(2) Except as described in paragraph (b)(4) of this section, FDA will not disclose the existence or contents of an FDA communication with an applicant regarding its application except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular FDA communication.

(3) Except as described in paragraph (b)(4) of this section, FDA will not disclose the existence or contents of information contained in an application unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence or contents of that particular information contained in an application, FDA may disclose the existence or contents of that particular information.

(4) If FDA refers an application to TPSAC, the contents of the application will be available for public disclosure, except information that is exempt from disclosure under part 20 of this chapter.

(c) *Disclosure of data and information after issuance of a marketing granted order.* After FDA issues a marketing granted order, it may make the following information related to the application and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the application and FDA's reviews of the application:

(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, unless 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 is appropriate for the protection of public health, unless the information 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, unless 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;

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

(6) Information and data contained in postmarket reports submitted to FDA, unless the information 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

(d) *Disclosure of data and information after the issuance of a marketing denial order.* After FDA issues a marketing denial order, FDA may make certain information related to the application and the order available for public disclosure upon request or at FDA's own initiative unless the information is otherwise exempt from disclosure under part 20 of this chapter. Information FDA may disclose includes, but is not limited to the tobacco product category (*e.g.*, cigarette), tobacco product subcategory (*e.g.*, filtered, combusted cigarette), package size, product quantity, characterizing flavor, and the basis for the marketing denial order.

§1114.49 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 application and all supporting information must be submitted in an electronic format that FDA can process, review, and archive.

(b) *Waivers from electronic format requirement.* An applicant may submit a written request, that is legible and 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 applicant. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobacco-products*). The request must include the following information:

(1) The name and address of the applicant, a list of individuals authorized by the applicant to serve as the contact person and contact information. If the applicant has submitted a PMTA previously, the regulatory correspondence should also include any identifying information about the previous submission.

(2) A statement that creation and/or submission of information in electronic format is not reasonable for the applicant, 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 a representative 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 application through the Document Control Center to the address provided in the FDA documentation granting the waiver.

PART 1140—CIGARETTES, SMOKELESS TOBACCO, AND COVERED TOBACCO PRODUCTS

Subpart A—General Provisions

Sec.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 21 Years of Age

Subpart C [Reserved]

Subpart D—Labeling and Advertising

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