DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1107

[Docket No. FDA–2016–N–3818]

RIN 0910–AH89

Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule to establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco product (SE Reports). The proposed rule would establish the information an SE Report must include so that FDA may make a substantial equivalence determination. In addition, the proposed rule would establish the general procedures FDA intends to follow when evaluating SE Reports, including procedures that would address communications with the applicant and the confidentiality of data in an SE Report. The proposed rule is intended to provide more clarity to applicants and support efficient and predictable reviews of SE Reports.

DATES: Submit either electronic or written comments on the proposed rule by June 17, 2019. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 2, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–3818 for ''Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways: Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Substantial Equivalence Reports for Tobacco Products.''

FOR FURTHER INFORMATION CONTACT: Annette Marthaler or Daniel Gittleson, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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Executive Summary

Purpose of the Regulatory Action

This proposed rule would establish requirements related to the content and format of SE Reports, including the information that SE Reports must contain. FDA is basing this proposed rule on the experience the Agency has in reviewing thousands of SE Reports since 2010. The SE Reports that FDA has seen to date range widely in the level of detail included. For example, some have very little information on the comparison of the new tobacco product with a predicate tobacco product while other SE Reports are much more detailed in describing how the new tobacco product compares to the identified predicate tobacco product and provide supporting information. This wide variation in the depth of content may be due, at least in part, to confusion about what information FDA needs from applicants to make a substantial equivalence finding. FDA's experience reviewing this wide range of SE Reports has been helpful in developing this proposed rule, which describes in detail the information that an applicant would be required to include in an SE Report.

The proposed rule also addresses issues such as communications with the applicant, the retention of records that support the SE Report, confidentiality of SE Report information, and electronic submission of the SE Report and amendments. The proposed rule is intended to provide both applicants and FDA with more certainty about the content and format of SE Reports and FDA's review of the SE Reports. The proposed rule is also intended to provide more clarity to applicants and help ensure that the SE pathway for premarket review of a new tobacco product is used when appropriate, *e.g.,* when there is a valid predicate tobacco product to which the new product can be scientifically compared and support efficient and predictable reviews.

Legal Authority

This proposed rule is being issued based upon FDA's authority to require premarket review of new tobacco products under sections 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387e(j) and 387j(a)), FDA's authority to require reports under section 909(a) of the FD&C Act (21 U.S.C. 387i(a)), FDA's authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c), as well as FDA's rulemaking and inspection authorities under sections 701(a) and 704 of the FD&C Act (21 U.S.C. 371(a) and 374).

Summary of the Major Provisions

This proposed rule would establish content and format requirements for SE Reports. Under the proposed rule, an SE Report must provide information comparing the new tobacco product to a predicate tobacco product, including information that would enable FDA to uniquely identify the new tobacco product and the predicate tobacco product. The proposed requirements would help ensure that an SE Report provides information necessary for FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

In addition, the proposed rule would explain how an applicant can amend or withdraw an SE Report, and explain how an applicant may transfer ownership of an SE Report to a new applicant. The proposed rule also would address FDA communications with applicants on SE Reports, including when FDA would issue deficiency notifications; explain FDA review cycles; and identify actions that FDA may take on SE Reports. The proposed rule would address when FDA may rescind an SE order and explain how long an applicant must maintain records related to the SE Report. The proposed rule also would explain FDA's disclosure provisions and provide for electronic submission of SE Reports, unless the applicant requests a waiver. FDA is basing the proposed rule on our experience reviewing SE Reports, and the proposed rule is intended to provide both applicants and FDA with more certainty related to the information needed to demonstrate substantial equivalence and FDA's review processes with the goal of an efficient and predictable review process for SE Reports.

Costs and Benefits

This proposed rule would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.60 million to $2.64 million, with a primary estimate of $1.61 million at a 3 percent discount rate, and from $0.56 million to $2.32 million, with a primary estimate of $1.43 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.07 million to $0.31 million, with a primary estimate of $0.19 million at a 3 percent discount rate and from $0.08 million to $0.33 million, with a primary estimate of $0.20 at a 7 percent discount rate.

The benefits of this proposed rule are potential time-savings to industry and cost-savings to government. This proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. In this proposed rule, we intend to shorten review times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this proposed rule would lead to better SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which would result in cost-savings. We estimate that the present value of government cost-savings ranges from $15 million to $198 million, with a primary estimate of $62 million at a 3 percent discount rate, and from $12 million to $163 million, with a primary estimate of $51 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.7 million to $23.2 million, with a primary estimate of $7.2 million at both 3 and 7 percent discount rates.

The qualitative benefits of this proposed rule include additional clarity to industry about the requirements for the content and format of SE Reports. The proposed rule would also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this proposed rule would make the SE pathway more predictable.

TABLE 1—SUMMARY OF ANNUALIZED COSTS AND BENEFITS OF THE PROPOSED RULE

[$2016 over 10 years]

	Low (3%)	Medium (3%)	High (3%)	Low (7%)	Medium (7%)	High (7%)
Costs	$0.07	$0.19	$0.31	$0.08	$0.20	$0.33
Benefits	1.7	7.2	23.2	1.7	7.2	23.2
Net Benefits (rounded)	1.7	7.1	22.9	1.7	7.0	22.9

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted June 22, 2009, and provided FDA the authority to regulate tobacco products under the FD&C Act. The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced into interstate commerce for commercial distribution in the United States, the new tobacco product must undergo premarket review by FDA. Section 910(a)(1) of the FD&C Act defines a ''new tobacco product'' as: (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.

The FD&C Act establishes three premarket review pathways for a new tobacco product:

- Submission of a premarket tobacco application under section 910(b);
- Submission of a report intended to demonstrate that the new tobacco product is substantially equivalent to a predicate tobacco product under section 905(j)(1)(A) (''SE Report''); and
- Submission of a request for an exemption under section 905(j)(3) (implemented at § 1107.1 (21 CFR 1107.1)).

Under section 910(a)(2)(B) of the FD&C Act, a manufacturer of a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, that submitted an SE Report [1] prior to March 23, 2011, may continue to market the tobacco product unless FDA issues an order that the tobacco product is not substantially equivalent. For any new tobacco product introduced into commercial distribution on or after March 22, 2011, or for which a substantial equivalence report was not submitted by March 23, 2011, a manufacturer must first submit a premarket application under section 910 for the new tobacco product to FDA, and FDA must issue an order authorizing the commercial distribution of the new tobacco product or find the product exempt from the requirements of substantial equivalence under section 910(a)(2)(A) of the FD&C Act, before the product may be introduced into commercial distribution. If a new tobacco product is marketed without an order or a finding of exemption from substantial equivalence, it is adulterated under section 902 of the FD&C Act and misbranded under section 903 of the FD&C Act and subject to enforcement action.

Since 2010, FDA has received more than 5,000 premarket applications. Almost all of the premarket applications have been SE Reports. To assist manufacturers in preparing SE Reports, FDA has issued guidance documents; [2] conducted Webinars; met with manufacturers; posted technical project lead reviews (which describe the administrative, compliance, and substantive scientific reviews completed on a specific SE Report), general information about not substantially equivalent (NSE) determinations, and orders (FDA posts the NSE orders for provisional tobacco products,[3] and SE orders for all tobacco products); and issued letters outlining deficiencies in individual tobacco product SE Reports. Manufacturers are now more informed about what an SE Report should contain, and FDA is more informed about the range of tobacco products and changes made to these products and the data needed to demonstrate substantial equivalence. The proposed rule is based on this experience and would establish requirements related to the substantial equivalence premarket pathway and provide both manufacturers and FDA with more certainty related to the information needed to demonstrate substantial equivalence and FDA's review processes.

II. Legal Authority

As described in the following paragraphs, FDA is proposing this rule to prescribe the content, form, and manner of reports intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product, as well as to establish other requirements related to SE Reports including requirements for keeping records, making reports, and providing information essential to FDA's implementation of the FD&C Act. In accordance with section 5 of the Tobacco Control Act, FDA intends that the requirements that would be established by this proposed rule be severable and that the invalidation of any provision of this proposed rule would not affect the validity of any other part of this rule.

Section 910(a)(2) of the FD&C Act requires a new tobacco product to be the subject of a premarket tobacco application (PMTA) order unless FDA has issued an SE order authorizing its commercial distribution or the tobacco product is exempt from substantial equivalence. To satisfy the requirement of premarket review, a manufacturer may submit a report intended to demonstrate the substantial equivalence of a new tobacco product to a predicate tobacco product under section 905(j) of the FD&C Act. Section 905(j) provides that FDA may prescribe the form and

[1] In this proposed rule, FDA refers to ''SE applications'' as ''SE Reports,'' but the terms both refer to a premarket submission under section 905(j)(1)(A) of the FD&C Act.

[2] The guidance documents include: ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products'' (January 2011); ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (September 2014); ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' (December 2016); and ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (July 2016). These guidance documents may be accessed at *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

[3] ''Provisional'' tobacco products refer to those tobacco products that were first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to March 22, 2011, and for which a 905(j) (Substantial Equivalence) Report was submitted no later than March 22, 2011.

manner of the substantial equivalence report, and section 910(a)(4) requires that as part of the 905(j) report, the manufacturer provide an adequate summary of any health information related to the new tobacco product or state that such information will be made available upon request.

Based on the information provided by the applicant, section 910(a)(3)(A) of the FD&C Act authorizes FDA to issue an order finding substantial equivalence when FDA finds that the new tobacco product is in compliance with the requirements of the FD&C Act and either: (1) Has the same characteristics as the predicate tobacco product or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under (the premarket tobacco application or ''PMTA'' provisions) because the product does not raise different questions of public health.

Section 909(a) of the FD&C Act authorizes FDA to issue regulations requiring tobacco product manufacturers or importers to maintain such records, make such reports, and provide such information as may be reasonably required to assure that their tobacco products are not adulterated or misbranded and to otherwise protect public health.

Under section 902(6)(A) of the FD&C Act, a tobacco product is adulterated if it is required to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i) of the FD&C Act. Under section 903(a)(6) of the FD&C Act, a tobacco product is misbranded if a notice or other information respecting it was not provided as required by section 905(j) of the FD&C Act. In addition, a tobacco product is misbranded if there is a failure or refusal to furnish any material or information required under section 909 (section 903(a)(10)(B) of the FD&C Act).

Section 701(a) of the FD&C Act gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act, and section 704 of the FD&C Act provides FDA with general inspection authority.

III. Description of Proposed Regulations

The proposed rule would add subparts B through E to current part 1107 of Title 21. The requirements set out in this proposed rule would not apply to provisional SE Reports or to any SE Report submitted before the effective date of any final rule associated with this proposed rulemaking. FDA has published a final rule extending the Agency's ''tobacco product'' authorities in the FD&C Act to all categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such newly deemed tobacco products (''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28974, May 10, 2016) (the Deeming final rule)). This proposed rule would apply to SE Reports for all tobacco products submitted after the final rule is effective, including the newly deemed tobacco products, that FDA regulates under Chapter IX of the FD&C Act. Proposed subparts D and E set out FDA's review processes and would be applicable to FDA's review of SE Reports after the effective date of any final rule. The proposed rule also would amend § 16.1 (21 CFR 16.1) to add a reference to proposed § 1107.50 (this proposed section would address rescission of an SE order).

A. General (Proposed Subpart B)

1. Scope (Proposed § 1107.10)

According to proposed § 1107.10, subparts B through E would establish the procedures and requirements for the submission of an SE Report under sections 905 and 910 of the FD&C Act, the basic criteria for establishing substantial equivalence, and the general procedures FDA intends to follow when evaluating SE Reports.

2. Definitions (Proposed § 1107.12)

Proposed § 1107.12 sets forth the meaning of terms as they apply to proposed subparts B through E of part 1107. Proposed § 1107.12 includes the following definitions from the FD&C Act:

- *Additive.* As defined in section 900(1) of the FD&C Act (21 U.S.C. 387), ''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.

An additive can be a type of ingredient in a tobacco product; an example is methyl salicylate in smokeless tobacco, which can serve as an absorption enhancer and affect the characteristics of the tobacco product by changing the rate of absorption into the body. Tobacco is not an additive.

- *Brand.* As defined in section 900(2) of the FD&C Act, ''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, identifiable pattern of colors, or any combination of such attributes.
- *Characteristic.* As defined in section 910(a)(3)(B) of the FD&C Act, ''characteristic'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product. All of the terms used in the definition of characteristic (materials, ingredients, design, etc.) are defined in proposed § 1107.12.
- *Distributor.* As defined in section 900(7) of the FD&C Act, ''distributor'' means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.
- *New tobacco product.* As defined in section 910(a)(1) of the FD&C Act, ''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.

Under the FD&C Act, and as reflected in the proposed definition, new tobacco products include those that are new because they have been rendered new through 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 (21 U.S.C. 387j(a)(1)(B)). For example, modifications to cigarette paper, container closure systems (*e.g.,*

change from glass to plastic e-liquid vials or from plastic to tin container closures), product quantity, specifications that change characteristics (*e.g.,* a modification to a different tobacco cut size) would render a tobacco product new.

Manufacturers sometimes co-package tobacco products. Co-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product. Examples include a carton of cigarette packs and a variety pack of three smokeless tins shrink-wrapped together where the cigarette packs and smokeless tins, respectively, could be legally marketed separately. However, if a manufacturer wishes to co-package two or more tobacco products (including their respective container closure systems), premarket review is required for any new tobacco product that the manufacturer intends to include in the co-package. An example includes shrink-wrapping grandfathered tobacco filler (in its unmodified container closure system) with new rolling papers; here premarket authorization would be required for the rolling papers. In addition, co-packaging two or more tobacco products within the same container closure system results in a new tobacco product, unless such co-packaged product is grandfathered. Examples include an RYO kit where rolling papers are placed inside the tin of tobacco filler and shrink-wrapping together two soft-packs of cigarettes, neither of which had been individually shrink-wrapped prior to being co-packaged. FDA invites comment on approaches to its review of these types of SE Reports, including, where relevant, how co-packaging products impacts consumer use and behavior.

In addition, for purposes of determining whether a tobacco product is new under section 910 of the FD&C Act, and therefore requires premarket authorization prior to marketing, a ''tobacco product'' can be considered to encompass the whole product (*e.g.,* a pack of cigarettes or a tin of loose tobacco), and is not limited to a single unit or portion of the whole product (*e.g.,* a single cigarette or a single snus pouch). *See Philip Morris USA Inc.* v. *U.S. Food & Drug Admin.,* 202 F. Supp. 3d 31, 55–57 (D.D.C. 2016). Consequently, a change in product quantity (*e.g.,* decreasing the weight of a smokeless package from 24 grams to 15 grams) results in a new tobacco product subject to premarket review since such a modification ''necessarily entails a change in the amount of the constituent ingredients and additives within the tobacco product, including nicotine'' (id. at 56).

FDA also considers a tobacco product marketed exclusively in test markets on February 15, 2007, to be a new tobacco product that is subject to premarket review by FDA. In addition, such test marketed products cannot serve as valid predicate products in an SE Report. A tobacco product that the applicant intends to test market after February 15, 2007, is also a new tobacco product subject to premarket review under section 910(a) of the FD&C Act because it was not commercially marketed in the United States as of February 15, 2007.

Because the terms ''test marketing'' and ''commercially marketed'' are not interchangeable, FDA is considering whether it would be useful to applicants for the rule to further expand on or define the terms ''test marketing'' and ''commercially marketed.'' Specifically, FDA is considering whether to add the following definition of test marketing: ''test marketing'' means distributing or offering for sale (which may be shown by advertisements, etc.) a tobacco product in the United States for the purpose of determining consumer response or other consumer reaction to the tobacco product, with or without the user knowing it is a test product, in which any of the following criteria apply:

- Offered in a limited number of regions;
- Offered for a limited time; or
- Offered to a chosen set of the population or specific demographic group.

FDA is considering whether to define ''commercially marketed'' as offering a tobacco product for sale to consumers in all or in parts of the United States. Factors FDA may consider include advertising or other means used to communicate that the tobacco product was available for purchase, including dated advertisements, dated catalog pages, dated promotional material, dated trade publications, dated bills of lading, dated freight bills, dated waybills, dated invoices, dated purchase orders, dated manufacturing documents, inventory lists, or any other document that demonstrates that the product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. FDA invites comment on what evidence would be sufficient to demonstrate that a product was commercially marketed (other than in test markets) as of February 15, 2007.

FDA is inviting comments on: (1) Whether the rule should further expand on the interpretation or include definitions of these terms, (2) the substance of the definitions, if included, and (3) whether or not the approach described is adequate to protect the public health.

- *Package or packaging.* As defined in section 900(13) of the FD&C Act, ''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. A subset of package is the container closure system (also defined in this proposed rule). For example, the carton holding multiple soft packs of cigarettes is considered the package, and each soft pack with surrounding cellophane is considered the container closure system. Packaging that constitutes the container closure system is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product (*e.g.,* leaching substances that are then incorporated into a tobacco product), but packaging that is not the container closure system is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of the tobacco product.
- *Substantial equivalence or substantially equivalent.* As defined in section 910(a)(3)(A) of the FD&C Act, the term ''substantial equivalence'' or ''substantially equivalent'' means, with respect to the tobacco product being compared to the predicate tobacco product, that FDA, by order, has found that the tobacco product:
  - Has the same characteristics as the predicate tobacco product or
  - Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA that demonstrates that it is not appropriate to require premarket review under section 910(a), (b) and (c) of the FD&C Act because the product does not raise different questions of public health.

FDA notes that this proposed rule does not include a proposed interpretation of ''same characteristics'' and ''different characteristics'' under section 910(a)(3)(A) of the FD&C Act.[4] However, FDA recognizes that stakeholders have requested additional clarity on these terms. FDA continues to consider the appropriate implementation of these terms, as well as public feedback the Agency has received on the terms during workshops

[4] FDA notes that products with identical characteristics are not new products, and thus are not required to undergo premarket review.

and in response to other **Federal Register** notices (*e.g.,* most recently, in response to a notice related to the Paperwork Reduction Act, 83 FR 45251, September 6, 2018). For example, FDA is considering whether the ''same characteristics'' prong might be appropriate for new tobacco products that are so similar to the predicate product that FDA would not need scientific information to determine whether the new product raises different questions of public health. Examples of changes between the new and predicate products that might be appropriate to proceed through ''same characteristics,'' either individually or in combination, include, non-exhaustively: (1) A change in product quantity between the new and predicate tobacco products; (2) a change in container closure system for non-moist tobacco products; (3) decreases in the total amount of tobacco in the new tobacco product without any corresponding changes in other ingredients or characteristics of the new tobacco product; and (4) changes in the non-combusted portion of a cigarette, for example, a change in tipping paper color from plain to cork, or a change in adhesive, or the removal of a dye or ink.

Under this approach, a new product would have ''different characteristics'' if a product were dissimilar enough from the predicate product that FDA could not determine without scientific information whether the new product raised different questions of public health. Examples of changes between the new and predicate products that might be appropriate to proceed through ''different characteristics,'' either individually or in the aggregate, include, non-exhaustively:

- A change in filter or ventilation of a combusted tobacco product, because such a change has the potential to affect the public health analysis required to assess substantial equivalence, such that FDA would need scientific information to determine whether the new product raises different questions of public health. For example, in some circumstances, a change in filter could result in an increase in ventilation and a change in harmful or potentially harmful constituent (HPHC) exposure levels to the user, with effects on the public health impact of the product. It is possible that in some other circumstances, a change in filter would not have results that would affect the public health impact of the product.
- A change in container closure system for a moist smokeless tobacco product, because FDA would need scientific information to determine, for example, whether or not such differences could result in a change in tobacco product stability that would increase HPHC levels and exposures to the user.
- A change in characterizing flavor in the new product because FDA would need scientific information to determine, for example, whether or not such differences could affect use behaviors.

FDA notes that these examples are illustrative only and are not intended to convey that any differences specific to an individual case would or would not be appropriate to proceed through the ''different characteristics'' approach or result in a determination of SE.

When a new product has different characteristics, FDA would evaluate whether the difference(s) in characteristics, individually and in the aggregate, do not cause the new product to raise different questions of public health. In determining if a new product raises different questions of public health, FDA may consider, among other things, whether one or more of the following is the case, as compared to the predicate product, (1) the new product has the potential to increase HPHC yields, and, if so, the degree of such an increase; (2) the new product has the potential to increase toxicity; (3) the new product has the potential to increase initiation; (4) the new product has the potential to increase abuse liability; (5) the new product has the potential to increase dependence; or (6) the new product has the potential to decrease cessation. Based on this analysis, FDA will determine whether the applicant has demonstrated that any differences do not cause the new product to raise different questions of public health.

Please note that FDA is including these examples based on the Agency's experience to date in reviewing SE reports, and for purposes of soliciting comments on this approach, and FDA will continue to review each SE Report and make an SE determination on the basis of the information included in that SE Report. FDA invites comment on the terms ''same characteristics'' and ''different characteristics,'' the potential approach discussed above, and any alternative approaches to interpretation of these terms, including examples of new tobacco products that would have the ''same characteristics'' as the predicate, as well as new tobacco products that would have ''different characteristics'' from the predicate. While the rule proposes that certain information would be required for reports submitted under either the same characteristics or different characteristics prong, we welcome comments on what information would need to be included under either or both prongs if the approach described above, or an alternative approach, is implemented. FDA also invites comment on how we might evaluate different questions of public health. In your comment, please include your reasoning for how you would distinguish the scope of the same characteristics prong from the different characteristics prong, *i.e.,* when an applicant might claim that a proposed new tobacco product is substantially equivalent to a predicate tobacco product because it has the ''same'' characteristics. FDA will consider all comments and will seek to provide additional clarity in the final rule, if possible.

- *Tobacco product.* As defined in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), the term ''tobacco product'' means any product that is made or derived from tobacco 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 is a drug under section 201(g)(1), a device under section 201(h), or a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)). As explained in the definition of ''new tobacco product,'' FDA 's interpretation is that the tobacco product encompasses the whole product and is not limited to a single unit or portion of the whole product.
- *Tobacco product manufacturer.* As defined in section 900(20) of the FD&C Act, the term ''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. FDA interprets ''manufactures, fabricates, assembles, processes, or labels'' as including, but not being limited to: (a) Repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package; (b) reconstituting tobacco leaves; or (c) applying any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist. Manufacturing activities typically do not include the activities of de-stemming, drying, or packaging tobacco leaves; mechanically removing foreign material from tobacco leaves; and humidifying tobacco leaves with nothing other than potable water in the

form of steam or mist. A proposed definition for the term ''finished tobacco product'' is also included in the proposed rule.

In addition, FDA proposes the following definitions:

- *Accessory.* FDA proposes to define ''accessory'' as 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:
  - Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
  - Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but solely controls moisture and/or temperature of a stored product; or solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Examples of accessories are ashtrays and spittoons because they do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents, or characteristics of a tobacco product. Examples of accessories also include humidors or refrigerators that solely control the moisture and/or temperature of a stored product and conventional matches and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product. This proposed definition is also in accord with the definition included in the Deeming final rule.

- *Applicant.* FDA proposes to define ''applicant'' as any manufacturer of tobacco products who is subject to chapter IX of the FD&C Act that submits a premarket application to receive marketing authorization for a new tobacco product. For the purposes of part 1107, a premarket application refers to an SE Report or an exemption request.
- *Commercial distribution.* FDA proposes to define ''commercial distribution'' as any distribution of a tobacco product to consumers or to another person through sale or otherwise. This term does not include transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such products are not made available for consumption or resale. This term would exclude the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term ''commercial distribution'' has the same meaning except the term does not include distribution of any tobacco products that are neither imported nor offered for import into the United States. This term is intended to include a tobacco product that is test marketed after February 15, 2007, and this term would encompass distribution of free samples (*e.g.,* smokeless products). FDA intends to limit our enforcement of the requirements of section 910 and 905(j) to finished tobacco products (see the Guidance for Industry and FDA Staff entitled ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products'' (76 FR 789, January 6, 2011); see also Deeming final rule, 81 FR at 29019).
- *Component or part.* FDA proposes to define ''component or part'' as 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. A container closure system (which would also be defined in this proposed section) is considered a component or part. With respect to these definitions, FDA notes that ''component'' and ''part'' are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this proposed rule, FDA is using the terms ''component'' and ''part'' interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between ''component'' and ''part'' in the future. This proposed definition and approach are in accord with the Deeming final rule. FDA invites comments on this approach.
- *Composition.* FDA proposes to define ''composition'' as all of the materials in a tobacco product, including ingredients, additives, and biological organisms. The term also includes the manner in which these ingredients, additives, biological organisms, etc., are arranged and integrated to produce a tobacco product. Composition refers primarily to the chemical and biological properties of a tobacco product, whereas design refers to the physical properties of a tobacco product. A biological organism refers to any living biological entity, such as an animal, plant, fungus, or bacterium.
- *Constituent.* FDA proposes to define ''constituent'' as 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 from a tobacco product, or any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product. Examples of constituents include harmful or potentially harmful constituents, total particulate matter, nicotine-free dry particulate matter, and water. A constituent also could include any other chemical or chemical compound contained in or produced by a tobacco product under conditions of use.
- *Container closure system.* FDA proposes to define ''container closure system'' as any packaging materials that are a component or part of a tobacco product.

Examples of a container closure system include the blister pack around a dissolvable tablet (in this example, if there is a box around a blister pack, the box is not considered a container closure system if it is not intended or reasonably expected to alter or affect the dissolvable tablet), the can that contains and protects a moist snuff product, and the plastic-wrapped hard pack or soft pack used to contain and protect cigarettes. In the context of determining whether a product is substantially equivalent as defined in section 910(a)(3)(A) of the FD&C Act, a container closure system is a component or part of a tobacco product because of its potential to alter or affect the performance, composition, constituents, or other physical characteristics of the product. For example, if a change in the container closure system could affect the chemistry of the product, FDA could require the applicant to demonstrate that the change in the container closure system does not cause the new tobacco product to raise different questions of public health. Although the FD&C Act does not itself define ''component'' or ''part,'' FDA recently promulgated definitions for these terms in the Deeming final rule. According to 21 CFR 1100.3, ''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.[5] The same definitions are also reflected in this rule's proposed § 1107.12.

In addition, considering a distinct subset of packaging (*i.e.,* container closure system) to be a component or part is consistent with the FD&C Act. For example, section 900(1) of the FD&C Act defines an ''additive'' as 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 substance 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. This definition further evinces Congress's understanding that packaging is not entirely separable from the tobacco product. Finally, the definition of ''package'' in section 900(13) of the FD&C Act does not dictate a contrary result, and can be reasonably interpreted to mean that a distinct subset of packaging is also a component or part of a tobacco product.

According to the proposed definition above, packaging constitutes a container closure system if it is intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product, even if it is also used to protect or contain the tobacco product. For example, packaging materials constitute a container closure system if substances within that packaging are intended or reasonably expected to affect product moisture, *e.g.,* when the manufacturer changes the package of a moist snuff from plastic to fiberboard, which can affect microbial stability and TSNA formation during storage. Another example of this is when menthol or other ingredients are applied to the inner foil to become incorporated into the consumed product (Ref. 1). Packaging materials may also be intended or reasonably expected to affect the characteristics of a tobacco product by impacting the rate of leaching into, and ultimately, the amount of substances found in, the consumable tobacco product. In fact, it has been demonstrated that compounds in packaging materials may also diffuse into snuff and affect its characteristics (Ref. 2). Thus, for example, packaging material that affects the characteristics of a tobacco product by impacting the moisture level or shelf life of a tobacco product is a container closure system (*e.g.,* a plastic versus a metal container of smokeless tobacco). A difference in tobacco moisture is reasonably expected to affect microbial growth in the product, extraction efficiency, and total exposure to nicotine or the carcinogens N-nitrosonornicotine (NNN) or 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (Ref. 26).

Treating a distinct subset of packaging as a component or part thus furthers the fundamental purpose of the Tobacco Control Act to protect the public health. This interpretation is also consistent with the broad definition of ''tobacco product,'' as well the definition of ''additive,'' which includes any substance that may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any tobacco product—and not just substances that do *in fact* have such effects. This shows that Congress did not intend for FDA to be required to show that a container closure system did in fact alter or affect the tobacco product's performance, composition, constituents, or other characteristics. Indeed, if FDA were to adopt a narrow construction of ''tobacco product'' to exclude these materials, the Agency's ability to evaluate whether the differences between the new and predicate tobacco product cause the new tobacco product to raise different questions of public health would be impeded, thereby leaving the Agency unable to fully execute its mission to protect the public health.

- *Design.* FDA proposes to define ''design'' to mean the form and structure concerning, and the manner in which, components or parts, ingredients, software, and materials are integrated to produce a tobacco product. This term refers to the physical properties of a tobacco product. Examples of design features include tip ventilation, paper porosity, tobacco cut width, and filter efficiency.
- *Finished tobacco product.* FDA proposes to define ''finished tobacco product'' to mean a tobacco product, including all components and parts, sealed in final packaging (*e.g.,* filters or filter tubes sold separately to consumers or as part of kits).
- *Grandfathered tobacco product.* FDA proposes to define a ''grandfathered tobacco product'' to mean a tobacco product that was commercially marketed in the United States on February 15, 2007. This term does not include tobacco products exclusively marketed in a test market as of that date. FDA interprets the phrase ''as of February 15, 2007,'' as meaning that the tobacco product was commercially marketed in the United States ''on February 15, 2007,'' and the proposed definition reflects this interpretation (see the final guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the FD&C Act.
- *Harmful or potentially harmful constituent* (HPHC). FDA proposes to define ''harmful or potentially harmful constituent'' as any chemical or chemical compound in a tobacco product or tobacco smoke or emission that: (1) Is or that potentially could be inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission and (2) causes or has the potential to cause direct or indirect harm to users or nonusers of tobacco products.

FDA has previously discussed HPHCs in FDA guidance documents (see the final guidance entitled ''Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act'' (76 FR 5387, January 31, 2011; revised guidance issued August 2016)). The current established list of HPHCs can be found on FDA's website at *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297786.htm* (77 FR 20034, April 3, 2012). In addition, since the inception of the SE program for tobacco products, HPHCs have been considered ''other features,'' and the proposed definition of ''other features'' in this rule would include HPHCs (see the final guidance entitled ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products,'' (January 5, 2011)).

- *Health information summary.* FDA proposes to define ''health information summary'' to mean a summary, submitted by the applicant under section 910(a)(4) of the FD&C Act, of any health information related to the new tobacco product. This would

[5] ''Accessory'' is defined as 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 solely controls moisture and/or temperature of a stored tobacco product or solely provides an external heat source to initiate but not maintain combustion of a tobacco product (§ 1100.3).

include detailed information concerning adverse health effects of the new tobacco product. For example, information concerning adverse health effects includes specific adverse events that have been reported to the applicant and also includes any research or data concerning adverse health effects of which the applicant is aware.

- *Health information statement.* FDA proposes to define ''health information statement'' to mean a statement, made under section 910(a)(4) of the FD&C Act that health information related to the new tobacco product would be made available upon request by any person. Like the health information summary, the health information provided to a person requesting it would be required to include any health information related to the new tobacco product, including detailed information regarding data concerning adverse health effects of the new tobacco product.
- *Heating source.* FDA proposes to define ''heating source'' as the source of energy that is used to burn or heat a tobacco product. An example of a heating source is a flame.
- *Ingredient.* FDA proposes to define ''ingredient'' as tobacco, substances, compounds, or additives 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. For example, an ingredient may be a single chemical substance, leaf tobacco, or the product of a reaction, such as a chemical reaction, in manufacturing. Examples of substances and compounds (ingredients) reasonably expected to be formed through a chemical reaction during tobacco product manufacturing include the following:
  - The reaction of sugars with amines to form families of compounds with new carbon-nitrogen bonds, including Maillard reaction products and Amadori compounds.
  - The reaction of sodium hydroxide with citric acid to form sodium citrate.
  - The production of ethyl alcohol, a residual solvent, from ethyl acetate during production of tipping paper adhesive.
  - Products of thermolytic reactions, such as the production of carboxylic acids from sugar esters.
  - Products of enzymatically or nonenzymatically catalyzed reactions, such as the hydrolytic production of flavor or aroma precursors from nonvolatile glucosides.
  - Products of acid-base reactions, such as removal of a proton from protonated nicotine to generate the basic form of nicotine (''free'' nicotine).
- *Material.* FDA proposes to define ''material'' to mean an assembly of ingredients. Materials are assembled to form the tobacco product or components or parts of tobacco products. For example, material would include the glue or paper pulp for a cigarette where the paper pulp includes multiple ingredients (*e.g.,* multiple types of tobacco, water, and flavors) assembled into the paper (or pulp depending on the water content).
- *Other features.* FDA proposes to define ''other features'' to mean any distinguishing qualities of a tobacco product similar to those specifically enumerated in section 910(a)(3)(B) of the FD&C Act. The definition would include: (1) HPHCs (note that the definition of new tobacco product includes any modification to any constituents, including smoke constituents, section 910(a)(1)(B) of the FD&C Act) and (2) any other product characteristics that relate to the chemical, biological, and physical properties of the tobacco product that are necessary for SE Report review. As described in the proposed definition of HPHC, HPHC information is necessary to provide a complete comparison between the new and predicate tobacco products: HPHCs are a subset of the chemical and chemical compounds in a tobacco product or tobacco smoke or emission. As such, HPHC information for the new and predicate tobacco products is necessary for FDA to determine whether the new tobacco product raises different questions of public health. Other features also would encompass other product characteristics that relate to the chemical, biological, and physical properties that would not be addressed as a material, ingredient, design, composition, or heating source.
- *Predicate tobacco product.* FDA proposes to define ''predicate tobacco product'' to mean a tobacco product that is a grandfathered tobacco product or a tobacco product that FDA has previously found to be substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act. This proposed definition is also based on language in section 905(j)(1)(A)(i) of the FD&C Act.
- *Submission tracking number or STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and requests for grandfather determinations.
- *Substantial equivalence report or SE Report.* FDA proposes to define ''substantial equivalence report'' (also known as a 905(j) report) or SE Report to mean a submission under section 905(j)(1)(A)(i) of the FD&C Act that includes the basis for the applicant's determination that a new tobacco product is substantially equivalent to a predicate tobacco product. This term includes the initial SE Report and all subsequent amendments (*e.g.,* amendments include information an applicant submits in response to a deficiency letter).

B. Substantial Equivalence Reports (Proposed Subpart C)

1. Submission of a Substantial Equivalence Report (Proposed § 1107.16)

Proposed § 1107.16 explains the basic timeframes that would be required for submitting an SE Report to FDA before commencing commercial distribution of a new tobacco product. An applicant may submit an SE Report to demonstrate that a new tobacco product is substantially equivalent to a predicate tobacco product (an applicant could also consider whether the exemption under § 1107.1 or an application under section 910(b) of the FD&C Act is a more appropriate premarket pathway for the applicant's new tobacco product). If an applicant chooses to submit an SE Report for a new tobacco product, it must do so at least 90 calendar days before the date the applicant intends to begin commercial distribution of the product (see section 905(j)(1) of the FD&C Act). The proposed rule also provides that an applicant may not begin commercial distribution of the new tobacco product that is the subject of the SE Report until FDA has issued an order stating that the Agency has determined that the new tobacco product is substantially equivalent to a predicate tobacco product (unless the new tobacco product has received authorization to be marketed through another premarket pathway, *i.e.,* PMTA or exemption from substantial equivalence). Otherwise, the new tobacco product is both adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act) and subject to enforcement action.

2. Required Content and Format of an SE Report (Proposed § 1107.18)

Since March 22, 2011 (the date that SE Reports for provisional tobacco products were required to be submitted), FDA has gained considerable experience in reviewing more than 3,000 SE Reports submitted under sections 905(j) and 910(a) of the FD&C Act. As a result, FDA has identified information essential to the review of SE Reports, which is reflected

in the content and format requirements of proposed § 1107.18.

a. *Overview.* Proposed § 1107.18(a) provides an overview of the requirements for the content and format of an SE Report. Proposed § 1107.18(a) would provide that the SE Report include information that would enable FDA to uniquely identify the new tobacco product and the predicate tobacco product and compare the new tobacco product to a predicate tobacco product. This information is necessary for FDA both in reviewing the SE Report so that we can understand the comparison and also to issue an order that appropriately identifies the tobacco product that is subject to the order. Providing sufficient information as described in proposed § 1107.18 would help enable FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (as required by section 910(a)(2)(A) of the FD&C Act).

The proposed provision would require that the SE Report contain the following elements:

- General information (described in proposed § 1107.18(c));
- Summary (described in proposed § 1107.18(d));
- New tobacco product description (described in proposed § 1107.18(e));
- Predicate tobacco product description (described in proposed § 1107.18(f)). This would include a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the STN of the SE order finding the predicate tobacco product SE, or the STN of, or specific information sufficient to support, a grandfathered determination of the predicate tobacco product. If the SE Report includes information on the grandfathered status of the predicate tobacco product (but FDA has not yet made a grandfathered determination [6]), FDA would make the grandfathered determination before beginning substantive scientific review of the SE Report to ensure that the predicate tobacco product is valid;
- Comparison information (described in proposed § 1107.18(g));
- Comparative testing information (described in proposed § 1107.18(h))
- Statement of compliance with applicable tobacco product standards under section 907 of the FD&C Act (21 U.S.C. 387g) (described in proposed § 1107.18(i));
- Health summary or statement regarding the availability of such information as required by section 910(a)(4) of the FD&C Act (described in proposed § 1107.18(j));
- Compliance with part 25 (21 CFR part 25) (environmental impact considerations) (described in proposed § 1107.18(k)); and
- Certification statement (described in proposed § 1107.18(*l*)).

If the SE Report were missing any of these items, the Agency would, under proposed § 1107.44(a), refuse to accept the SE Report for review.

b. *General Format.* Proposed § 1107.18(b) provides the general requirements for the format of the SE Report and would require the applicant to submit the SE Report with the appropriate FDA form (Refs. 3 and 4). Proposed § 1107.18(b) would require the SE Report and any amendments to contain a comprehensive index and table of contents and be well organized, legible, and written in the English language. For any foreign language documents, the original foreign language document must be accompanied by the English translation and a certification by the applicant or responsible official authorized to represent the applicant that the translation into English is accurate. The comprehensive index would include the listing of files and data associated with those files (*e.g.,* for an SE Report that is electronically submitted, the comprehensive index would include the listing of files and associated metadata).

As described in proposed § 1107.62, FDA is proposing that, for an SE Report and supporting documents to be accepted by FDA, the SE Report and documents must be submitted to FDA in an electronic format that the Agency can process, read, review, and archive, unless the Agency has previously granted a waiver from these requirements. FDA will not act on an SE Report until the Center for Tobacco Product's (CTP's) Document Control Center has received an SE Report that the Agency can process, read, review, and archive. Applicants that are unable to submit their reports in electronic format would be advised to consult proposed § 1107.62, which explains how the applicant may obtain a waiver from the electronic filing requirement. FDA intends to provide information on our website about technical specifications related to submission, including the electronic formats, which would allow FDA to process, read, review, and archive the SE Report. Providing technical specifications information on our website enables FDA to periodically update the electronic formats that we are capable of accepting so that we can accommodate quickly evolving technology.

The requirements in proposed § 1107.18(b) and 1107.62 are intended to address some of the problems we have seen with SE Reports. For example, some SE Reports have been submitted to FDA in a proprietary format or password protected without providing FDA access or password information. Following up with an applicant to obtain access or password information takes time and contributes to delays. In addition, some electronic submissions have not been in a static format, and thus, the pages reformat, renumber, re-bullet, or re-date each time the document is accessed. Receiving SE Reports with these issues affects our ability to cross-reference, share, and efficiently evaluate information. Lastly, because FDA is required under regulations governing Federal records to maintain many files long term, and in a ''sustainable'' format (for more information on sustainable formats, please refer to National Archives and Record Administration Bulletin 2014–04, *https://www.archives.gov/records-mgmt/bulletins/2014/2014-04.html*), proposed § 1107.18(b) would ensure that these files can be managed, opened, and read by the Agency for the duration of the retention period.

c. *General information.* Proposed § 1107.18(c) lists the information that the SE Report would be required to include. This information includes general administrative information that must specify the type of submission (*e.g.,* SE Report); the new tobacco product with unique identification and the predicate tobacco product with unique identification (to enable us to identify the new tobacco product as well as identify the predicate product), as well as contact information. The SE Report must include the following information using the FDA-provided forms, as appropriate:

- The date the SE Report is submitted (using the applicant-generated submittal date, *i.e.,* the date the applicant assigns to it, which for a paper submission is the date typically located at the top of a cover letter, and for an electronic submission is the date when the document is uploaded to FDA's electronic submission system);
- Type of submission (*e.g.,* SE Report or amendment to an SE Report);
- Previously assigned FDA STN, where applicable (*e.g.,* in cases where

[6] FDA discusses the information the Agency will consider, along with Agency's general thinking on grandfathered determinations, in the guidance document, ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014).

the applicant is submitting an amendment to an SE Report, the Agency has assigned a number in advance, or the applicant is referencing a previously denied SE Report);

- Any other relevant FDA STN, such as a request for a grandfathered determination, and cross-references to meetings regarding the new tobacco product (*e.g.,* if FDA issues an order denying marketing authorization for a tobacco product and meets with the applicant about it before the applicant submits a new SE Report, the meeting should be referenced in the new SE Report);
- The name, address, and contact information for the applicant and the authorized representative or authorized U.S. agent (for a foreign applicant). FDA would require identification of an authorized representative or, for foreign applicants, authorized U.S. agent to help FDA ensure adequate notice is provided to applicants of official Agency communications. In particular, FDA may be unable to confirm that adequate notice of Agency action or correspondence concerning premarket submissions is provided to foreign applicants as FDA cannot necessarily confirm receipt of correspondence sent internationally. Accordingly, the designation of a U.S. agent provides an official contact to the Agency who can receive the information or documentation on behalf of the applicant. Providing notice regarding that SE Report to the U.S. agent would constitute notice to the foreign applicant. FDA requires identification of a U.S. agent to assist FDA in communicating with the foreign applicant and help permit the Agency to efficiently process SE Reports and avoid delays. In many instances during the SE Report review process, FDA has reached out numerous times to a foreign applicant and has either been unable to speak with the applicant or was unable to directly communicate questions and/or concerns. This impediment has resulted in delays or terminations in the review of specific SE Reports and a slowdown of the premarket application process as a whole. A U.S. agent would act as a communications link between FDA and the applicant and would facilitate timely correspondence between FDA and foreign applicants, including responding to questions concerning pending applications and, if needed, assisting FDA in scheduling meetings with the foreign applicants to resolve outstanding issues before agency action is taken. In addition, the authorized representative or U.S. agent would be authorized to act on behalf of the applicant for that specific SE Report.
- For both the new and predicate tobacco product, information needed to uniquely identify the products, including:
  - The manufacturer;
  - Product name, including the brand and sub brand;
  - Product category; product subcategory; and product properties, as provided in table 2. The applicant would select and provide for both the new and predicate tobacco products the appropriate category, subcategory, and product properties (if the product does not have a listed product property, *e.g.,* ventilation or characterizing flavor, the report must state ''none'' for that property):

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION

Tobacco product category	Tobacco product subcategory	Product properties
Cigarettes	Combusted, Filtered	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 millimeter (mm), 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s)[7] (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Combusted, non-filtered	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Characterizing Flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Combusted, Other	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Non-Combusted (e.g., a cigarette where the tobacco is only heated not burned).	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 cigarettes, 25 cigarettes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing Flavor(s) (e.g., none, menthol). —Source of energy (e.g., charcoal, electrical heater). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Cigarette, Co-Package	—For a new co-packaged tobacco product composed of multiple cigarette tobacco products, include, as applicable, all properties for each individual tobacco product, as identified above.
Roll-Your-Own (RYO) Tobacco Products.	RYO Tobacco Filler	—Package type (e.g., bag, pouch).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Product quantity (e.g., 20 g, 40 g). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Rolling Paper	—Package type (e.g., bag, box, booklet). —Product quantity (e.g., 50 sheets, 200 papers). —Length (e.g., 79 mm, 100 mm, 110 mm). —Width (e.g., 28 mm, 33 mm, 45 mm). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Filtered Cigarette Tube	—Package type (e.g., bag, box). —Product quantity (e.g., 100 tubes, 200 tubes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Non-Filtered Cigarette Tube	—Package type (e.g., bag, box). —Product quantity (e.g., 100 tubes, 200 tubes). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Filter	—Package type (e.g., bag, box). —Product quantity (e.g., 100 filters, 200 filters). —Length (e.g., 8 mm, 12 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Paper Tip	—Package type (e.g., bag, box). —Product quantity (e.g., 200 tips, 275 tips). —Length (e.g., 12 mm, 15 mm). —Width (e.g., 27 mm). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	RYO Co-Package	—For a new co-packaged tobacco product composed of multiple RYO tobacco products, include, as applicable, all properties for each individual tobacco product (e.g., RYO tobacco, rolling paper, filtered cigarette tube, non-filtered cigarette tube, filter, paper tip) as identified above.
	Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product.
Smokeless Tobacco Products	Loose Moist Snuff	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 grams (g), 2 ounces). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Portioned Moist Snuff	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). ——Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 2 g/piece). —Portion length (e.g., 15 mm, 20 mm). —Portion width (e.g., 10 mm, 15 mm). —Portion thickness (e.g., 5 mm, 7 mm). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Loose Snus	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Product quantity (e.g., 20 g, 2 ounces). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Portioned Snus	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 pouches, 20 pieces). —Portion mass (e.g., 1.5 g/pouch, 2 g/piece). —Portion length (e.g., 15 mm, 20 mm). —Portion width (e.g., 10 mm, 15 mm). —Portion thickness (e.g., 5 mm, 7 mm). —Tobacco cut size (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Loose Dry Snuff	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 g, 2 ounces). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Dissolvable	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 22.5 g, 20 g). —Portion count (e.g., 15 sticks, 20 tablets). —Portion mass (e.g., 1.5 g/strip, 1.0 g/piece). —Portion length (e.g., 10 mm, 15 mm). —Portion width (e.g., 5 mm, 8 mm). —Portion thickness (e.g., 3 mm, 4 mm). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Loose Chewing Tobacco	—Package type (e.g., bag, pouch, wrapped). —Product quantity (e.g., 20 g, 3 ounces). —Tobacco cut size (e.g., 0.05 mm, 0.07 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Portioned Chewing Tobacco	—Package type (e.g., plastic can with metal lid, plastic can with plastic lid). —Product quantity (e.g., 20 g). —Portion count (e.g., 10 bits). —Portion mass (e.g., 2 g/bit). —Portion length (e.g., 8 mm, 10 mm). —Portion width (e.g., 6 mm, 8 mm). —Portion thickness (e.g., 5 mm, 7 mm). —Characterizing flavor(s) (e.g., none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Smokeless Co-Package	—For a new co-packaged tobacco product composed of multiple smokeless tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
ENDS (Electronic Nicotine Delivery System).	Open E-Liquid (e.g., an e-liquid in a bottle with a removable cap).	—Package type (e.g., bottle, box). —Product quantity (e.g., 1 bottle, 5 bottles). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (e.g., 10 ml). —Nicotine concentration (e.g., 0, 0.2 mg/ml). —PG/VG ratio (e.g., N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	Closed E-Liquid (e.g., a sealed cartridge for use in an e-cigarette).	—Package type (e.g., cartridge). —Product quantity (e.g., 1 cartridge, 5 cartridges). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (e.g., 10 ml). —Nicotine concentration (e.g., 0, 0.2 mg/ml). —PG/VG ratio (e.g., N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Closed E-Cigarette (e.g., a cigalike).	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Length (e.g., 100 mm, 120 mm). —Diameter (e.g., 6 mm, 8 mm). —E-liquid volume (e.g., 2 ml, 5 ml). —Nicotine concentration (e.g., 0, 0.2 mg/ml). —PG/VG ratio (e.g., N/A, 0/100, 50/50). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —Additional properties needed to uniquely identify the tobacco product.
	Open E-Cigarette (e.g., a tank system).	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Length (e.g., 100 mm, 120 mm). —Diameter (e.g., 8 mm, 14 mm). —E-liquid volume (e.g., 2 ml, 5 ml). —Wattage (e.g., 100 W, 200 W). —Battery capacity (e.g., 100 mAh, 200 mAh). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	ENDS Component	—Package type (e.g., box, none, plastic clamshell). —Product quantity (e.g., 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	ENDS Co-Package	—For a new co-packaged tobacco product composed of multiple ENDS tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	ENDS Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product.
Cigars	Filtered, Sheet-Wrapped Cigar	—Package type (e.g., hard pack, soft pack, clam shell). —Product quantity (e.g., 20 filtered cigars, 25 filtered cigars). —Characterizing flavor (e.g., none, menthol). —Length (e.g., 89 mm, 100 mm). —Diameter (e.g., 6 mm, 8.1 mm). —Ventilation (e.g., none, 10%, 25%). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Unfiltered, Sheet-Wrapped Cigar	—Package type (e.g., box, film sleeve). —Product quantity (e.g., 1 cigar, 5 cigarillos). —Characterizing flavor (e.g., none, menthol). —Length (e.g., 100 mm, 140 mm). —Diameter (e.g., 8 mm, 10 mm). —Tip (e.g., none, wood tips, plastic tips). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Leaf-Wrapped Cigar	—Package type (e.g., box, film, sleeve, none). —Product quantity (e.g., 1 cigar, 5 cigars). —Characterizing flavor (e.g., none, whiskey). —Length (e.g., 150 mm, 200 mm). —Diameter (e.g., 8 mm, 10 mm).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
		—Wrapper material (e.g., burley tobacco leaf, Connecticut shade grown tobacco leaf). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	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).
	Cigar Tobacco Filler	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20 g, 16 ounces). —Characterizing flavor (e.g., none, tobacco, menthol, cherry). —Tobacco cut size (e.g., 5 mm, 10 mm). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Cigar Co-Package	—For a new co-packaged tobacco product composed of multiple cigar tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
Pipe Tobacco Products	Pipe	—Package type (e.g., box, none). —Product quantity (e.g., 1 pipe). —Length (e.g., 200 mm, 300 mm). —Diameter (e.g., 25 mm). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Pipe Tobacco Filler	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20 g, 16 ounces). —Characterizing flavor(s) (e.g., none, menthol, Cavendish, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Pipe Component	—Package type (e.g., bowl, shank, stem, screen, filter). —Product quantity (e.g., 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Pipe Co-Package	—For a new co-packaged tobacco product composed of multiple pipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
Waterpipe Tobacco Products	Waterpipe	—Package type (e.g., box, none). —Product quantity (e.g., 1 waterpipe). —Length (e.g., 200 mm, 500 mm). —Width (e.g., 100 mm, 300 mm). —Number of hoses (e.g., 1, 2, 4). —Characterizing flavor(s) (e.g., none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Waterpipe Tobacco Filler	—Package type (e.g., bag, pouch). —Product quantity (e.g., 20 g, 16 ounces). —Characterizing flavor(s) (e.g., none, tobacco, menthol, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Waterpipe Heat Source	—Package type (e.g., box, film sleeve, bag, none). —Product quantity (e.g., 150 g, 680 g). —Characterizing flavor(s) (e.g., none, menthol, apple). —Portion count (e.g., 20 fingers, 10 discs, 1 base). —Portion mass (e.g., 15 g/finger). —Portion length (e.g., 40 mm, 100 mm). —Portion width (e.g., 10 mm, 40 mm). —Portion thickness (e.g., 10 mm, 40 mm). —Source of energy (e.g., charcoal, battery, electrical). —Additional properties needed to uniquely identify the tobacco product (if applicable).

TABLE 2—TOBACCO PRODUCT CATEGORY, SUBCATEGORY, AND PRODUCT PROPERTIES INFORMATION—Continued

Tobacco product category	Tobacco product subcategory	Product properties
	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, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	Waterpipe Co-Package	—For a new co-packaged tobacco product composed of multiple waterpipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified above.
	Waterpipe Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other	Other	—Package type (e.g., bag, box). —Product quantity. —Characterizing flavor(s) (e.g., none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

[7] Characterizing flavors may include those added to certain components or parts (*e.g.,* paper) of the tobacco product. If there is no characterizing flavor, the application must state ''none.''

The applicant would be required to include any additional properties needed to uniquely identify the tobacco product, if applicable (*e.g.,* use of product descriptors such as ''premium'' would be required to be identified). Proposed § 1107.18(c)(8) would also require the address of the facilities involved in the manufacture of the tobacco products and any Facility Establishment Identifier number. This information would assist the Agency in making environmental impact considerations and determinations under part 25 by helping FDA understand the scale of products that would be manufactured.

d. *Summary.* Proposed § 1107.18(d) would require a summary at the beginning of the SE Report. This summary portion of the SE Report would act as an abstract designed to orient reviewers to the contents of the SE Report. Under proposed § 1107.18(d), the summary would be required to include three elements. First, the summary would be required to include a concise description of the characteristics of the new tobacco product. As stated in section 910(a)(3)(B) of the FD&C Act, characteristics means ''the materials, ingredients, design, composition, heating source, or other features of a tobacco product,'' all of which are defined in proposed § 1107.12. Second, the summary would also be required to include the applicant's basis for whether the new tobacco product has the same characteristics as the predicate tobacco product or has different characteristics from the predicate tobacco product which the applicant believes do not cause the new tobacco product to raise different questions of public health. Third, with respect to those characteristics, the summary would be required to include a description of the similarities and differences between the new tobacco product and the predicate tobacco product.

e. *New tobacco product description.* Proposed § 1107.18(e) sets forth the information that would be required in the description of the new tobacco product. Based on our experience reviewing SE Reports, FDA has found that, to have a meaningful scientific comparison, a new tobacco product should be compared to a single predicate product (this is discussed in more detail at proposed § 1107.18(f), the section of this document describing the predicate tobacco description). Accordingly, proposed § 1107.18(e) would require the applicant to identify the new tobacco product in the SE Report for comparison to one predicate tobacco product. As is currently the practice, applicants may continue to bundle groups of SE Reports submitted under proposed § 1107.18 that have the same proposed modifications (*e.g.,* a change in ingredient supplier that results in a new tobacco product). As discussed previously, co-packaging two or more tobacco products may result in a new tobacco product.

Proposed § 1107.18(e) would require that the SE Report describe the new tobacco product in sufficient detail to enable FDA to understand and evaluate the characteristics of the new tobacco product in comparison to the predicate. Specifically, the Agency proposes that this section of the SE Report include the following information:

- A narrative description of the new tobacco product, as well as detailed drawings or schematics. The drawings would be required to identify the container closure system and illustrate all of the product's components. As defined in proposed § 1107.12, a ''component or part'' of a tobacco product is 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. The definition excludes anything that is an accessory of a tobacco product. For example, an applicant submitting an SE Report for a pouched snus product would illustrate all the components and parts of the product, including the pouch material and tobacco filler. The narrative description would identify all the components, *e.g.,* for a cigarette, the applicant would identify the rod, and the rod's paper and filler, and so on.
- A description of and the function for each component or part of the new tobacco product as well as an explanation of how each component or part is integrated into the product design.
- If the manufacturing process for the new tobacco product could affect the characteristics of the new product, an applicant would be required to provide an overview of the manufacturing process. This overview would not need to be an exhaustive discussion but enough information to enable FDA to fully understand and compare the characteristics that can be affected by the manufacturing process of the new

tobacco product and the predicate tobacco product. FDA has found during reviews of SE Reports that changes in manufacturing, including fermentation, may impact the characteristics of the tobacco product, *e.g.,* the quantities of nicotine (total and free), as well as HPHCs such as tobacco-specific N-nitrosamines (TSNAs). Such changes could cause the new product to raise different questions of public health, *e.g.,* fermentation can increase the levels of nicotine, which impacts dependence and cessation (Refs. 36 and 37), and an increase in TSNAs may increase the risk for certain types of cancer (Ref. 38). Thus, if fermentation is used in the manufacturing process for the new tobacco product, then the SE Report would be required to describe the process, including the type and quantity of the microbial inoculum and/or fermentation solutions (fermentation is typically used in smokeless tobacco products, and the hot and sticky environment associated with fermentation may contribute to bacteria and growth of contaminants, which is a major health and safety concern). If the manufacturing process for the new tobacco product does not affect the characteristics of the new product beyond what is described elsewhere in the SE Report, an applicant would be required to state that to satisfy this provision.

f. *Description of the predicate tobacco product.* Under proposed § 1107.18(f), the SE Report would be required to include a section describing the predicate tobacco product. Under proposed § 1107.18(f)(1), the applicant would be required to identify one predicate tobacco product that is either a grandfathered tobacco product or a tobacco product that FDA previously found to be substantially equivalent to a predicate tobacco product. The applicant may reference the STN if FDA has already made a grandfathered determination, or provide specific information sufficient to support a grandfathered determination (see the final guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' (79 FR 58358, September 29, 2014)). If the SE Report includes information to demonstrate the grandfathered status of the predicate product, FDA intends to make the grandfathered determination on that predicate tobacco product before beginning substantive scientific review of the SE Report.

As with any new tobacco product, applicants who wish to use the SE pathway to obtain marketing authorization for new co-packaged products would have to identify a single predicate tobacco product for each new tobacco product. An applicant could use a co-packaged product as a predicate so long as it is a valid predicate; however, an applicant would not be required to use a co-packaged product as its predicate tobacco product.

FDA invites comments on this approach or any recommended alternative approaches for co-packaged products.

Proposed § 1107.18(f)(2)(i) would require that the predicate tobacco product chosen by the applicant be in the same category (*e.g.,* cigarette, smokeless) and subcategory (*e.g.,* filtered, non-filtered) as the new tobacco product to provide a meaningful starting point for our substantial equivalence review. This proposed requirement reflects FDA's experience, which has been that if the predicate and new tobacco products differ on these points, it is highly unlikely that we would be able to find that the SE Report demonstrates the substantial equivalence of the new tobacco product to the predicate tobacco product. For example, when an SE Report includes a predicate and new tobacco product that are in different categories (*e.g.,* a comparison of a combusted tobacco product to a smokeless product), the considerable differences between the products in almost every characteristic will raise different questions of public health (*e.g.,* an applicant attempting to compare a smokeless moist snuff predicate to a new combusted filtered cigarette would likely not be able to demonstrate that the cigarette does not raise different questions of public health as compared to the smokeless moist snuff, as the properties and characteristics of the two products are so vastly different. For example, an applicant would not be able to show that a ventilation of 25 percent would not cause the cigarette to raise different questions of public health given that the smokeless moist snuff has no ventilation characteristic with which to compare). These drastic differences in characteristics make it very hard for applicants to provide the evidence necessary to show that these differences do not cause the new product to raise different questions of public health because addressing the uncertainty in the influence on adverse health impact on the user, product use, initiation, and cessation would often require complex clinical studies.

In addition, under proposed § 1107.18(f)(2)(ii), the predicate must have been either commercially marketed (not exclusively in a test market) in the United States as of February 15, 2007 (a grandfathered predicate tobacco product), or have been previously determined to be substantially equivalent by FDA. If the SE Report is using a grandfathered predicate tobacco product, the SE Report must include a statement that ''I, (name of responsible official), confirm that the predicate tobacco product, (insert name of predicate tobacco product), was commercially marketed other than for test marketing as of February 15, 2007'' or reference the STN for a previous determination by FDA that the predicate tobacco product is grandfathered. The statement would be a means of ensuring that the applicant understands that the product must have been commercially marketed on February 15, 2007, to be considered grandfathered, and supports the information provided in proposed § 1107.18(f)(1).

Under proposed § 1107.18(f)(2)(iii), the applicant would be required to identify a predicate tobacco product that is an individual product. As previously discussed, an applicant could use a co-packaged product as a predicate so long as it is a valid predicate (*e.g.,* on the market as of February 15, 2007, or one that was previously found SE). However, a predicate could not be a fictional product made up by combining characteristics of two or more products that are grandfathered or have been found SE. In addition, under proposed § 1107.18(f)(2)(iv) and (v), the predicate tobacco product could not be the subject of a rescission order by FDA as described in proposed § 1107.50 and could not have been removed from the market at the initiative of FDA or have been determined by judicial order to be adulterated or misbranded. These proposed requirements are intended to minimize some of the problems with predicate tobacco products that FDA has identified during SE Report reviews which prevent us from proceeding with an SE review.

g. *Comparison information.* Proposed § 1107.18(g) states that the SE Report would be required to include a comparison of the characteristics of the new tobacco product and the predicate tobacco product, as described in proposed § 1107.19. FDA expects this comparison to be a significant part of an SE Report as it would be expected to describe in detail how the product characteristics of the new tobacco product compare to the product characteristics of the predicate tobacco product.[8] If the new tobacco product

[8] FDA notes that some applications may use surrogate tobacco products for discrete parts of an SE application. A surrogate is a tobacco product for which an applicant provides data it would like to

has some characteristics that are not identical to the predicate, but some characteristics that are identical, the applicant must provide comparison information related to the characteristics that are not identical, but may certify that the other characteristics are identical under proposed § 1107.18(*l*)(2).

For example, if the modification between the new and predicate product is a change to fire standard compliant (FSC) paper, the SE Report would state and provide comparison information on the difference of the non-FSC to FSC paper, the change in filtration (*e.g.,* if there is a change in filtration due to the change made to the paper), and the change in tobacco blend (*e.g.,* if there is a change in blend made with the change to the paper), but the SE Report could then include a certification that all other characteristics of the new and predicate product, other than the modified paper, filtration, and blend, are identical. Another example is a change in product quantity (*e.g.,* an increase from 20 grams to 35 grams of loose moist snuff). In this scenario, if the per weight composition has not changed, the applicant could provide comparison information on only the characteristics that differ between the new and predicate product, and include a certification under proposed § 1107.18(*l*)(2) that all other characteristics are identical. A third example would be a container closure system (CCS) substitution of a bag for a box. In this case, the SE Report would provide comparison information on the change in CCS and the SE Report could then include a certification under proposed § 1107.18(*l*)(2) that the characteristics of all non-CCS items have not changed (*e.g.,* rolling papers are identical between the new and predicate product). The applicant would be required to maintain records supporting the certification consistent with proposed § 1107.58.

h. *Comparative testing information.* Other than for characteristics that are identical (and for which the applicant has certified that the characteristics are identical under paragraph (*l*)(2)), proposed § 1107.18(h) would require the SE Report to include testing information on the characteristics of the new and predicate tobacco products as described in section § 1107.19, except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product: (1) Has the same characteristics as the predicate or (2) does not raise different questions of public health. For example, it may not always be necessary to provide comparative testing information on the heating source.

Comparative testing supports the SE Report by showing the information contained in the SE Report is meaningful and accurate and, where applicable, helps demonstrate that the different characteristic(s) in a new tobacco product does not raise different questions of public health. FDA's experience has been that the summary data provided in some SE Reports has been miscalculated, and thus, a substantial equivalence determination was not supportable. To ensure the accuracy of the data provided, FDA has needed to review the experimental data.

Accordingly, proposed § 1107.18(h)(1) would require that the SE Report include test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results). Under proposed § 1107.18(h)(2), the testing would be required to be conducted on a sufficient sample size and on samples that reflect the final tobacco product composition and design. Proposed § 1107.18(h)(3) would require the SE Report to state whether the testing method for the new and predicate products are the same and, if they differ, to explain how the results of the different test methods can be compared. Under proposed § 1107.18(h)(4), the SE Report also must identify any national and international standards used to test the new and predicate tobacco products and explain any deviations.[9] If no standards were used for testing, the SE Report would be required to state so. There are multiple ways to satisfy this comparative testing requirement that may not require comparative testing on the specific characteristic that is different between the new and predicate tobacco product. For example, if an applicant is proposing to modify the container closure system of a smokeless tobacco product for loose moist snuff, rather than supply testing information on the container closure system, the applicant could demonstrate that the ingredients, constituents, moisture, and stability of the loose tobacco within the container closure system are not affected by the change in container closure system in a way that would cause the new product to raise different questions of public health. As testing information on the ingredients, constituents, moisture, and stability information would already be required for the smokeless tobacco product, additional comparative testing information on differences in the container closure system would not be required. Instead the applicant would state that this information is already covered by the submission of the ingredients, constituents, moisture, and stability information within the SE Report.

i. *Statement of compliance with applicable tobacco product standards.* As required by section 905(j)(1)(B) of the FD&C Act, under proposed § 1107.18(i), the SE Report must list and describe the action(s) that the applicant has taken to comply with the requirements under section 907 of the FD&C Act (tobacco product standards) that are applicable to the tobacco product. In the alternative, the SE Report must state that there are no requirements under section 907 that are applicable to the new tobacco product. For SE Reports that are submitted after the finalization of this rule, but still pending after issuance of any future tobacco product standards, FDA invites public comments on how such pending SE Reports should be considered or handled in relation to the satisfaction of the requirement for a statement of compliance with applicable tobacco product standards.

j. *Health information summary or statement regarding availability of such information.* As required by section 910(a)(4) of the FD&C Act, the SE Report must include either an adequate summary of any health information related to the new tobacco product or a statement that such information would be made available upon request by any person. Proposed § 1107.18(j) would codify this statutory requirement and ensure that applicants provide adequate information as required by section 910(a)(4). Under proposed § 1107.18(j)(1), if the applicant chooses to provide a health information summary, the applicant would be required to provide a redacted version of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and

extrapolate to the new, predicate tobacco product or both new and predicate tobacco products. However, the surrogate tobacco product is neither the new or predicate tobacco product (a grandfathered determination is not necessary for surrogate tobacco products as it is not a predicate tobacco product). Data for a surrogate tobacco product is provided in place of data or to provide a bridge between data for the new or predicate tobacco product. A surrogate tobacco product is used when there is inadequate data available for the new or predicate tobacco product; data for a surrogate tobacco product supplement the data for a new or predicate tobacco product. Unlike predicate tobacco products, surrogate tobacco product data may be in place at the start of substantive scientific review or may be provided in response to a deficiency letter. FDA invites comments on the use of surrogate tobacco products.

[9] In the guidance document entitled, ''Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products'' (January 2011), FDA provided some examples of standards that might be used to support an SE application.

20.63 (21 CFR 20.61 and 20.63). FDA believes that an SE Report redacted in the manner described would generally provide an adequate summary of any health information related to the new tobacco product, as well as detailed information regarding data concerning adverse health effects of the new tobacco product. The redacted SE Report would be required to be submitted with the original submission, and a redacted copy of an amendment would be required with the submission of any amendment to the SE Report.

In addition, to the extent that there is additional health information about the new tobacco product, including any information, research (*e.g.,* published or unpublished research, internal reports or analyses), or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report, the applicant would be required to provide such accurate and complete, and not false or misleading, information in the health information summary. If there is no such additional health information, the SE Report would be required to include a statement that the company does not have and does not know of any such additional health information. FDA would post the health information summary, including the redacted SE Report, and any additional health information provided by the applicant on FDA's website.

Under proposed § 1107.18(j)(2), if the applicant chooses to make the health information available upon request, the SE Report would be required to include a certification statement made by an authorized representative of the applicant that an adequate summary of any health information related to the new tobacco product, including detailed information regarding data concerning adverse health effects of the new tobacco product, would be made available to a requestor within 30 calendar days of a request. The certification is intended to ensure that applicants understand that they are responsible for providing this information upon request.

Under proposed § 1107.18(j)(3), the health information the applicant would need to make available would be a copy of the full SE Report (which includes any amendments), excluding research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63. To the extent that the applicant has or knows of any additional health information, including any information, research, or data regarding adverse health effects that is not contained in the SE Report, the applicant would also provide the requester such accurate and complete, and not false or misleading, information. If there is no such additional health information, the applicant would provide the requester with a statement that the company does not have and does not know of any such additional health information.

Proposed § 1107.18(j)(4) would provide that requests for health information be made to the authorized representative of the applicant, whose contact information the applicant would provide to FDA. FDA intends to make this contact information available on FDA's website. The applicant would be required to update this contact information with FDA whenever necessary (*e.g.,* the identified authorized representative is no longer with the company or the address or telephone information changes). If an applicant elects to include the statement in their SE Report, the applicant would be required to provide the information to persons who request it. Applicants would not be permitted to later amend SE Reports on which FDA has issued a marketing order to choose instead to submit a health information summary. Therefore, applicants that provide the statement instead of providing the summary to FDA as part of the SE Report must be prepared to provide the information required under section 910(a)(4) of the FD&C Act, as implemented through proposed § 1107.18(j).

Under proposed § 1107.18(j)(5), to the extent information is included in the health information summary or the health information provided upon request under paragraphs (j)(1) and (2) of this section that is not required by section 910(a)(4) of the Federal Food, Drug, and Cosmetic Act or paragraph (j) of this section, that information cannot contain a statement that would cause the proposed new tobacco product to be in violation of section 911 of the FD&C Act (21 U.S.C. 387k) upon the introduction or delivery for introduction of the proposed new product into interstate commerce. If an applicant includes such a statement in its health information summary or in the health information the applicant provides upon request, the review of the applicant's SE Report may be delayed.

FDA would generally not consider a statement of relative risk to be required by section 910(a)(4) of the FD&C Act or paragraph (j) of this section if the risk being conveyed is unrelated to the applicant's demonstration that the new product is substantially equivalent and FDA's review of the SE Report. For example, if an applicant submitted an SE Report for a new smokeless tobacco product and identified a smokeless tobacco product as the predicate product, a statement comparing the tar in the new smokeless tobacco product to the tar in a cigarette would generally be unrelated to the applicant's demonstration that the new product is substantially equivalent and FDA's review of the SE Report.

For the purposes of § 1107.18(j), any statement an applicant is required to include in a health information summary or the health information provided in response to a request—including statements made in an SE Report (*e.g.,* comparisons of HPHCs between the new and predicate tobacco products)—typically would not cause the proposed new tobacco product to be in violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the proposed new product into interstate commerce. Congress required applicants to submit health information summaries with their SE Reports or to provide such information upon request. Nothing in section 911 of the FD&C Act suggests that Congress intended for that provision to impede an applicant's ability to fulfill its obligations under section 910(a)(4) of the FD&C Act.

k. *Compliance with part 25.* An applicant must include an environmental assessment (EA) prepared in accordance with § 25.40 or a valid claim of a categorical exclusion, if applicable. (Under § 25.15(a), all submissions requesting FDA action require the submission of either a claim of categorical exclusion or an EA.) In accordance with § 25.40(a), an environmental assessment must include, at a minimum, brief discussions of the need for the proposed action, of alternatives as required by section 102(2)(E) of the National Environmental Policy Act (NEPA), of the environmental impacts of the proposed action and alternatives, a listing of the agencies and persons consulted, and the relevant environmental issues relating to the use and disposal from use. Although applicants may wish to review the categorical exclusions specific to tobacco product applications at § 25.35, the only categorical exclusion currently available for an order authorizing the marketing of a new tobacco product is found at § 25.35(a), and applies only to orders finding provisional products substantially equivalent. If the applicant believes the action would qualify for an available categorical exclusion, the applicant would be required to state under § 25.15(a) and (d) that the action qualifies for a categorical exclusion, cite to the claimed exclusion, and state that to the applicant's knowledge no

extraordinary circumstances exist under § 25.21.

To evaluate the environmental impact (as described in § 25.40(a)), information that addresses the status of the new tobacco product relative to the predicate tobacco product would be required. Accordingly, the environmental assessment would be required to include a statement indicating whether the new tobacco product is intended to: (1) Replace the predicate tobacco product once the new tobacco product receives market authorization and is commercially marketed; (2) be a line extension of the predicate tobacco product; (3) be marketed along with the predicate product by the same manufacturer; and/or (4) be marketed along with the predicate tobacco product by a different manufacturer (*e.g.,* by a manufacturer other than the manufacturer of the predicate tobacco product). This statement would be included in the section on the need for the proposed action and would help FDA understand the environmental impact of an SE order by understanding the marketing intention for the new and predicate tobacco products. The marketing authorization of a new tobacco product may have a different impact if the new tobacco product is intended to be marketed along with the predicate tobacco product than if the new tobacco product is intended to replace a predicate tobacco product.

l. Certification statement. Proposed § 1107.18(*l*)(1) would require that an applicant include in the SE Report a specific statement certifying that the applicant would maintain all records to substantiate the accuracy of the report consistent with the record retention requirements in proposed § 1107.58, that, to the best of their knowledge, the information and accompanying submission are true and correct, no material fact has been omitted, the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that 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 (under 18 U.S.C. 1001). The certification is intended to provide FDA with additional assurance that the applicant has fully considered the SE Report and its contents, that the applicant believes there is a basis for making the findings required by section 910(a)(2) of the FD&C Act, and that the applicant understands the potential consequences of submitting false information to the U.S. Government.

In addition, under proposed § 1107.18(*l*)(2), if an SE Report states that the new tobacco product has certain characteristics that are identical to the predicate tobacco product (though not all characteristics, such that the product would not be ''new''), an applicant can choose to submit a certification in lieu of providing information for each characteristic of the new and predicate tobacco products. FDA would permit the applicant to certify that the other characteristics are identical as long as the applicant maintains supporting documentation, including the records demonstrating the comparison information detailed in proposed § 1107.19. The records would be required to be maintained consistent with proposed § 1107.58. The certification must be signed by an authorized representative of the applicant.

3. Comparison Information (Proposed § 1107.19)

This proposed section describes the comparison information that would be required in the SE Report. Comparative testing supports the SE Report by showing the information contained in the SE Report is meaningful and accurate; where applicable, the testing also helps demonstrate that the different characteristic(s) in a new tobacco product does not raise different questions of public health. FDA requests public comments on the quantitative and qualitative differences in each of the design parameters for each of the tobacco product categories identified below as well as data to support such values or characteristics.

a. *Product design.* Proposed § 1107.19(a) would require the SE Report to include descriptions of the product designs of the new and predicate tobacco products and identify any differences. This proposed section would require that the information be in a tabular format with a side-by-side comparison of each design parameter of the new and predicate tobacco products. The SE report would also be required to include for each design parameter a target value and range of acceptable values, actual measured value (if applicable), and ranges of measured values (if applicable) with units of measure. The report would also be required to include test data for each applicable design parameter. Proposed § 1107.19(a)(1)-(6) would establish the required design parameter information for the tobacco product category, as follows:

For cigarettes, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 3—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)	—Puff count.
—Cigarette circumference (mm)	—Cigarette draw resistance (mm H^2O).
—Cigarette draw resistance (mm H^2O)	—Tobacco filler mass (mg).
—Tobacco filler mass (mg)	—Tobacco moisture (%).
—Tobacco rod density (g/cubic centimeter (cm^3))	—Filter ventilation (%).
—Tobacco moisture (%)	—Cigarette paper base paper basis weight (g/m^2).
—Filter ventilation (%)	—Cigarette paper base paper porosity (CU).
—Tipping paper length (mm)	—Cigarette paper band porosity (CU).
—Cigarette paper base paper basis weight (g/meter squared(m^2))	—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 pressure drop (mm H^2O).
—Cigarette paper base paper porosity (CU)	
—Cigarette paper band porosity (CU)	
—Cigarette paper band width (mm)	
—Cigarette paper band space (mm)	

TABLE 3—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:
—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 length (mm) —Filter pressure drop (mm H^2O)	

FDA is proposing to require that these parameters be included for cigarettes because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in cigarette length may alter tobacco biomarker levels (Ref. 5).
- A difference in cigarette circumference may affect filter efficiency and, in turn, smoke constituent yields (Ref. 6).
- A difference in puff count can directly affect smoke constituent yields (Ref. 7).
- A difference in cigarette draw resistance may result in differences in the difficulty of pulling air through the tobacco rod and, in turn, affect smoke constituent yields (Ref. 8).
- A difference in tobacco filler mass may affect smoke constituent yields (Refs. 9 and 10).
- A difference in tobacco rod density may modify burn properties and smoke constituent yields (Refs. 11 and 12).
- A difference in tobacco moisture may affect puff count (Refs. 13–15).
- A difference in cigarette paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).
- A difference in cigarette paper base paper porosity may affect smoke constituent yields (Ref. 16).
- A difference in cigarette paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 18, 19, and 38).
- A difference in cigarette paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).
- A difference in cigarette paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).
- A difference in filter efficiency may affect smoke constituent yields (Refs. 18 and 20).
- A difference in denier per filament may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
- A difference in total denier may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
- A difference in filter density may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
- A difference in filter pressure drop may affect smoke constituent yields (Ref. 23, slide 40).
- A difference in filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
- A difference in filter ventilation may affect smoke constituent yields (Ref. 6).
- A difference in tipping paper length may affect smoke constituent yields (Ref. 24).

For portioned and non-portioned smokeless tobacco products, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 4—REQUIRED DESIGN PARAMETER INFORMATION FOR PORTIONED AND NON-PORTIONED 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) —Tobacco moisture (%) —Portion length (mm) (if applicable) —Portion width (mm) (if applicable) —Portion mass (mg) (if applicable) —Portion thickness (mm) (if applicable). —Pouch paper wicking. —Pouch paper porosity (CU). —Pouch paper basis weight (g/m^2).	—Tobacco cut size (mm). —Tobacco moisture (%). —Portion mass (mg) (if applicable). —Pouch paper porosity (CU). —Pouch paper basis weight (g/m^2).
Non-portioned Smokeless Tobacco Products	
—Tobacco cut size (mm). —Tobacco moisture (%).	—Tobacco cut size (mm). —Tobacco moisture (%).

FDA is proposing to require that these parameters be included for smokeless tobacco products because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in tobacco cut size may alter the surface area and accessibility of saliva to get to the surfaces of the tobacco, thereby affecting the amount and rate of constituents released from the product (Ref. 25).
- A difference in tobacco moisture may affect microbial growth in the product, extraction efficiency, and total exposure to nicotine, NNN, and NNK (Ref. 26).

• A difference in portion mass may affect user exposure to the tobacco product and, in turn, exposure to the HPHCs contained in each portion (Ref. 27).

• A difference in portion length as it relates to portion size may affect the amount of constituents in each portion (Ref. 27).

• A difference in portion width may result in a surface area difference, which is proportional to the amount and rate of constituents released from the product (Ref. 28).

• A difference in portion thickness may result in a surface area difference, which is directly proportional to the amount and rate of constituents released from the product (Ref. 28).

• A difference in pouch paper basis weight may alter the interactions between the tobacco and oral cavity, thereby affecting the amount and rate of constituents released from the product (Ref. 29).

• A difference in pouch paper porosity may alter the interactions between the tobacco and oral cavity, thereby affecting the amount and rate of constituents released from the product (Ref. 29).

For RYO tobacco rolling papers, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 5—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:
—Paper length (mm). —Paper width (mm). —Mass per paper (mg). —Cigarette paper base paper basis weight (g/m)^2. —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU) (if applicable). —Cigarette paper band width (mm) (if applicable). —Cigarette paper band space (mm) (applicable).	—Mass per paper (mg). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU) (if applicable).

FDA is proposing to require that these parameters be included for rolling papers because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

• A difference in overall length may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 23, slide 46).

• A difference in overall width may alter the surface area that is available for tobacco packing, thereby affecting the smoke constituent yields (Ref. 23, slide 46).

• A difference in total mass per pack may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 16 and 23 (slide 46)).

• A difference in RYO paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).

• A difference in RYO paper base paper porosity may affect smoke constituent yields (Ref. 16).

• A difference in RYO paper band porosity may affect smoke constituent yields because band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 17 and 37).

• A difference in RYO paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).

• A difference in RYO paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).

For RYO tobacco tubes, the required design parameter information to be provided for each predicate and new tobacco product is as follows:

TABLE 6—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 length (mm). —Tube circumference (mm). —Total mass (mg). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU). —Cigarette paper band width (mm). —Cigarette paper band space (mm).	—Total mass (mg). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU).

For RYO tobacco filtered tubes, the required design parameter information to be provided for each new predicate and new tobacco product would be:

TABLE 7—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 length (mm). —Tube circumference (mm). —Total mass (mg). —Tipping paper length (mm).	—Total mass (mg). —Filter ventilation (%). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity (CU).

TABLE 7—REQUIRED DESIGN PARAMETER INFORMATION FOR RYO TOBACCO FILTERED TUBES—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:
—Filter ventilation (%). —Cigarette paper base paper basis weight (g/m^2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU). —Cigarette paper band width (mm). —Cigarette paper band space (mm). —Filter length (mm). —Filter denier per filament (DPF). —Filter total denier (g/9000m). —Filter density (g/cm^3). —Filter pressure drop (mm H^2O).	—Cigarette paper band porosity (CU). —Filter denier per filament (DPF). —Filter total denier (g/9000m). —Filter density (g/cm^3). —Filter pressure drop (mm H^2O).

FDA is proposing to require that these parameters be included for RYO tobacco tubes because variations in these parameters may cause the new tobacco product to raise different questions of public health, as described below:

- A difference in tube length may alter tobacco biomarker levels (Ref. 5).
- A difference in tube circumference may affect filter efficiency and, in turn, smoke constituent yields (Ref. 6).
- A difference in total mass per pack may be a result of a surface area or basis weight difference and, in turn, may affect puff count and smoke constituent yields (Refs. 16 and 23 (slide 46)).
- A difference in tube paper base paper basis weight may affect puff count and smoke constituent yields (Ref. 16).
- A difference in tube paper base paper porosity may affect smoke constituent yields (Ref. 16).
- A difference in tube paper band porosity may affect smoke constituent yields since band porosity allows for the overall assessment of the weighted change in air flow through the cigarette paper during active puffing (Refs. 17 and 37).
- A difference in tube paper band width may affect ventilation and, in turn, smoke constituent yields (Ref. 20).
- A difference in tube paper band space may affect ignition propensity and, in turn, puff count (Ref. 21).
- A difference in filter efficiency may affect smoke constituent yields (Ref. 13).
- A difference in denier per filament may affect filter efficiency and, in turn, smoke constituent yields (Ref. 22).
- A difference in total denier may affect filter efficiency and, in turn, smoke constituent yields (Ref. 33).
- A difference in filter density may affect filter efficiency and, in turn, smoke constituent yields (Ref. 32).
- A difference in filter pressure drop may affect smoke constituent yields (Ref. 23, slide 40).
- A difference in filter length may affect filter efficiency and, in turn, smoke constituent yields (Ref. 32).
- A difference in ventilation may affect smoke constituent yields (Ref. 24).
- A difference in tipping paper length may affect smoke constituent yields (Ref. 24).

For RYO tobacco, the required design parameter information to be provided for each predicate and new tobacco product would be:

TABLE 8—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 filler mass (mg). —Tobacco cut size (mm). —Tobacco moisture (%).	—Tobacco filler mass (mg). —Tobacco cut size (mm). —Tobacco moisture (%).

FDA is proposing to require that these RYO tobacco parameters be included for RYO tobacco because variations in these parameters may cause the new tobacco products to raise different questions of public health, as described below:

- A difference in tobacco filler mass may affect smoke constituent yields when used with rolling paper (Ref. 9).
- A difference in tobacco cut width alters the size of the tobacco pieces, which may result in more particulate matter (Ref. 30).
- A difference in moisture may affect smoke composition (Ref. 13).

For tobacco products not specifically identified (*e.g.,* ENDS, cigars) FDA invites comments and information on the parameters that may be needed to support an SE Report.

b. *Heating source.* Proposed § 1107.19(b) would require that the SE Report include a description of any heating source for both the new and predicate tobacco products (*e.g.,* burning coal, electric, chemical reaction, carbon tip) and identify any differences. If there is no heating source for the new and predicate tobacco products, the SE Report would be required to state that.

c. *Product composition.* Proposed § 1107.19(c) would require that the SE Report include descriptions of the product composition of the new and predicate tobacco products and identify any differences. The information would be required to be in tabular format with a side-by-side comparison of the materials and ingredients for each component or part of the new and predicate tobacco products. Under the proposed rule, the SE Report would be required to provide for each material and ingredient the following information: The quantity, the target value and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) reported as mass per component or part.

Proposed § 1107.19(c)(1) would require that the SE Report include the following information for each material in the product:

- The material name and common name (if applicable);
- The component or part where it is located;

- The subcomponent or subpart where it is located (if applicable);
- The function of the material;
- Quantities (including ranges or means and acceptance limits) with identification of any specification variation between the new tobacco product and predicate tobacco product;
- Specifications (including quality, grades, and suppliers) used for the new tobacco product and the predicate (including any specification variations, if applicable); and
- Any other material properties necessary to characterize the new and predicate tobacco products.

Proposed § 1107.19(c)(2) would require that the SE Report include information on ingredients other than tobacco (information on tobacco ingredients is addressed in proposed § 1107.19(c)(3)). Required information would include:

- International Union of Pure and Applied Chemistry chemical name and common name (if applicable);
- Chemical Abstracts Service (CAS) number(s) or FDA Unique Ingredients Identifier;
- The function of the ingredient;
- The quantity with the unit of measure (including ranges or means, and acceptance limits) of the materials in the new tobacco product and predicate tobacco product (with any specification variation, if applicable);
- The specifications (including purity or grade and supplier);
- For complex purchased ingredients, each single chemical substance reported separately; and
- Any other ingredient information necessary to characterize the new and predicate tobacco products.

Proposed § 1107.19(c)(3) would require information on tobacco ingredients. This information would include the following:

- The type of tobacco, including grade and variety. This impacts the characteristics of the products because different grades have different constituent profiles (the SE Report would need to include information on the applicant's grading system so that FDA understands the grade);
- The quantity, with the unit of measure (including ranges or means, and acceptance limits), of tobacco in the new and predicate tobacco products (with a specification variation, if applicable);
- The specification of tobacco used for the new tobacco product and predicate tobacco product (with any specific variation, if applicable);
- A description of any genetic engineering that impacts characteristics, because genetic engineering affects the constituent profile; and
- Any other information about tobacco ingredients necessary to characterize the new and predicate tobacco products.

If the new tobacco product does not contain tobacco (*e.g.,* rolling paper or tipping paper), this section of the report would be required to state that.

FDA is proposing that ingredient quantities under proposed § 1107.19(c)(2) and (3) be reported as mass per gram of tobacco for non-portioned tobacco products and as mass per portion for portioned tobacco products. These specific measurements provide consistent, complete information that would allow FDA to understand the ingredient quantities. In contrast, if ingredient quantities were reported as percentages, FDA would have to make assumptions about the denominator used to calculate the percentage. For example, if xylitol were reported as 10 percent of a portioned moist snuff, FDA would not able to determine if xylitol was 10 percent of the mass of the tobacco filler or of the entire product (containing filler, paper, etc.).

Proposed § 1107.19(c)(4) would require that the SE Report include a description of the container closure system for the new and predicate tobacco products, including a side-by-side quantitative comparison of the subcomponents or subparts and materials and annotated illustrations.

d. *Other features.* Proposed § 1107.19(d) would require that the SE Report include descriptions of any other applicable features of the new and predicate tobacco products and identify any differences that exist. If a specific feature described in proposed § 1107.19(d) is not applicable to the new tobacco product, the SE Report would be required to state as such. In response, FDA may request a scientific explanation for why a particular feature is not applicable, and under proposed § 1107.19(d) the applicant would be required to provide that information to FDA. The SE Report must also address any other product characteristics that relate to the chemical, physical or biological properties of the tobacco product and are necessary for SE Report review.

Specifically, proposed § 1107.19(d)(1) would require that the SE Report include HPHC and other constituent information as appropriate to demonstrate that: (1) The new tobacco product has the same characteristics as the predicate tobacco product or (2) any differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health, as follows:

- Constituent names in alphabetical order,
- Common names,
- CAS number,
- Mean quantity and variance with unit of measure,
- Number of samples and measurement replicates for each sample,
- Analytical methods used, description and associated reference(s),
- Testing laboratory(ies) and accreditation information,
- Length of time between dates of manufacture and dates of testing,
- Storage conditions of the tobacco product before it was tested, and
- Full test data (including test protocols, any deviations from the test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) for all testing performed.

For combusted tobacco products, constituent smoke yields from the new and predicate products would need to be determined using intense and non-intense smoking regimens.[10] Two smoking regimens are required in order to understand the way that constituent yields delivered by a tobacco product can change over a range of different smoking conditions. If constituent yields were only reported from a single smoking regimen, FDA would have limited and potentially misleading information about constituent yields produced by a given tobacco product. Many studies demonstrate that different smoking regimens result in different constituent yields from the same product (Refs. 31 and 32). By requiring both an intense and a non-intense smoking regimen, FDA would have a better understanding of quantities of each constituent that may be produced by the tobacco product when smoked under different conditions. If an alternative to these smoking regimens is used, the applicant would be required to provide an explanation of why the alternative provides comparable results to the intense and non-intense smoking regimens.

FDA is proposing that the HPHC information in an SE Report for a new cigarette include, at a minimum, a comparison of the quantities of nicotine-dry particulate matter, total particulate matter, carbon monoxide, and nicotine (total) in the mainstream smoke of the new tobacco product with that of the predicate tobacco product, using both intense and non-intense smoking regimens. Further, additional HPHC

[10] These refer to regimens by the International Organization for Standardization and Health Canada.

yields may need to be reported in order to demonstrate that: (1) The new tobacco product has the same characteristics as the predicate tobacco product or (2) any differences in characteristics do not cause the new tobacco product to raise different questions of public health. For example, blend differences may require reporting of HPHC yields specific to the differences in tobacco blends. Studies show that the mainstream smoke of burley and reconstituted tobaccos contains much higher TSNA levels than the mainstream smoke of bright and oriental tobacco, whereas the mainstream smoke of bright tobacco contains higher benzo[a]pyrene levels than other tobacco types (Refs. 33 and 34). Reconstituted tobacco can produce high levels of carbon monoxide, nitrogen oxides, and TSNAs during combustion (Ref. 8). Smoke from cigarettes made from expanded stems is higher in carbon monoxide, nitrous oxides, formaldehyde, tar, benzo[a]anthracene, and benzo[a]pyrene than smoke from cigarettes made of puffed tobacco, expanded tobacco, or freeze-dried tobacco (Ref. 30). Similarly, addition of sugar or corn syrup to a tobacco product may increase HPHCs such as formaldehyde and may therefore require additional HPHC measurements (Ref. 35). Or, if the new tobacco product contains significantly more guar gum (a binder in rod paper and tobacco blends) than the predicate product, additional HPHC yields may be required to be reported because pyrolysis of guar gum may form formaldehyde, acetaldehyde, acetone, benzene, cresol, and toluene (Refs. 39–41).

Based on its experience reviewing new tobacco products, FDA has found significant increases in HPHCs (*e.g.,* TSNAs and polycyclic aromatic hydrocarbons (PAHs)) in cigarettes due to changes in types of tobacco when compared to a predicate tobacco product. For all new cigarettes that have a substantial increase in other types of tobacco, to support a finding of SE the applicant should include a comparison of TSNAs and PAHs in the mainstream smoke of the new tobacco product with that of the predicate tobacco product using both intense and non-intense smoking regimens. Depending on the specific differences between the new and predicate products, quantities of additional HPHCs in mainstream smoke may be required to be reported.

For a smokeless tobacco product, the HPHC information in an SE Report would need to include a comparison of the quantities of total and free nicotine, total TSNAs, NNN, and NNK in the tobacco of the products. Depending on the specific differences between the new and predicate products, the applicant may be required to report quantities of additional HPHCs in the product.

Proposed § 1107.19(d)(2) would require that the SE Report include a description and comparison of any other features of the new and predicate tobacco products.

Proposed § 1107.19(e) would require stability information for smokeless tobacco products and any tobacco product that contains fermented tobacco. As described in more detail in the following paragraphs, stability information is a particular concern with smokeless tobacco products and other tobacco products that contain fermented tobacco because the characteristics of these products can be affected by the manufacturing process, storage conditions, and length of time on a shelf. Accordingly, proposed § 1107.19(e) would require stability information for the new and predicate tobacco products, including:

- A description of how stability is indicated and whether stability testing is identical for the predicate and new tobacco products (proposed § 1107.19(e)(i));
- Any known or expected impacts on product stability due to differences between the new and predicate products (if there are none, the SE Report would state that) (proposed § 1107.19(e)(ii)). For example, for products that contain fermented tobacco, the SE Report would be required to provide information on the fermentation processing steps, including the following:
  - Composition of the inoculum including species name(s) and concentration(s)
  - pH
  - Temperature
  - Moisture content
  - Water activity
  - Duration
  - Ingredients added.

FDA is proposing to require that this information be submitted in the SE Report because these parameters of the fermentation process can result in different degrees of change in the chemical constituents of the tobacco (Refs. 42 and 43) and affect the type and amount of microorganisms in the final product (Ref. 44), thereby affecting the stability of the product, which could change the characteristics of the tobacco product, which may cause the new tobacco product to raise different questions of public health. In addition, the type and amount of the fermentation inoculum can be used to control or affect the fermentation process and thus, can change the product as a result of directed fermentation, which could cause the new tobacco product to raise different questions of public health (Ref. 45).

- Detailed stability testing information, including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all stability testing performed (proposed § 1107.19(e)(iii)). Stability testing would be required to be performed at the beginning (zero time), middle, and end of the expected storage time for the following chemical and microbial endpoints:
  - Microbial content data, including total aerobic microbial count and total yeast and mold count, along with identification of detected microbiological organisms by genus and species names (if applicable)
  - pH
  - Moisture content
  - Water activity
  - Tobacco-specific nitrosamines (TSNAs, including total, NNN, and NNK)
  - Nitrate and nitrite levels
  - Preservatives and microbial metabolic inhibitors, if any
  - Method of heat treatment or pasteurization used to reduce microbial loads.

The proposed rule would require this information because product stability is affected by factors such as the fermentation and stabilization processes (if applicable), addition of chemical additives to control microbial activity (*e.g.,* preservatives, metabolic inhibitors, humectants), and water activity (a_w) of the product (Refs. 42, 46–48). Additionally, factors such as nitrate/nitrite concentrations, moisture content, microbial content, storage temperature, and pH are reported to influence the microbial stability and TSNA formation during storage of tobacco products (Refs. 49–53).

- Storage conditions for samples retained for testing, identifying the test methods used, along with testing of the tobacco product in the same container closure system as that in which the tobacco product is intended to be marketed, and testing supporting the expiration date (proposed § 1107.19(e)(iv)). Accelerated studies, combined with basic stability information, could be used to support tentative expiration dates provided full shelf life studies are not yet available but are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf-life studies, stability studies would need to be conducted to support the SE

Report, including tobacco product testing at appropriate intervals, until the tentative expiration date could be verified or the appropriate expiration date could be determined.

Proposed § 1107.19(e)(v) and (vi) would require information on the stability testing laboratory and identification of the microbiological organisms by genus and species names, where applicable, along with the culture collection number either used during the manufacturing process and/or detected through stability testing.

Proposed § 1107.19(f) would require applicants to state that the new tobacco product has either: (1) The same characteristics as the predicate tobacco product and the basis for this determination or (2) different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (see § 1107.19(a)); heating source (see § 1107.19(b)); materials and ingredients (see § 1107.19(c)); and other features (see § 1107.19(d)). In addition, in order to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any differences in the manufacturing process that could affect the characteristics of the new product do not cause the new product to raise different questions of public health (see § 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (see § 1107.19(e)).

Proposed § 1107.19(g) would explain that, if the applicant is comparing the new tobacco product to a predicate product that FDA has previously found to be substantially equivalent to another product, FDA may request that the applicant include information related to the original grandfathered tobacco product. Although an applicant can support a showing of SE by comparing the new tobacco product to a tobacco product that is grandfathered or that FDA has previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). This statutory provision helps FDA ensure that new tobacco products using the substantial equivalence pathway and relying on predicate tobacco products previously found SE do not vary so much from the original grandfathered tobacco product that the new product would actually raise different questions of public health compared to the originally grandfathered tobacco product. New products with differences that may appear only incremental when a new tobacco product is compared to a predicate product previously found SE may actually have had significant changes when compared to the grandfathered tobacco product.

Because the statute permits applicants to compare to either a grandfathered tobacco product or one that FDA has previously found SE (section 905(j)(1)(A)(i)) but also requires FDA to make an SE determination by comparing the new tobacco product to the grandfathered tobacco product (section 910(a)(2)(A)(i)(I)), FDA is proposing the approach in § 1107.19(g). To meet its statutory obligation, FDA may need to look back to previously submitted SE Reports in the SE chain that rely on the original grandfathered product in order to issue an SE order. Manufacturers have been on notice since the passage of the Tobacco Control Act that FDA must make the comparison between the new tobacco product and the original grandfathered tobacco product, and in doing so, may need to rely on previously submitted SE Reports, even if submitted by a different manufacturer than the applicant at hand.

Accordingly, for SE Reports that compare the new tobacco product to a predicate tobacco product that FDA previously found substantially equivalent, proposed § 1107.19(g) states that, if requested by FDA, the applicant would be required to provide information related to the original grandfathered tobacco product, even if the grandfathered tobacco product is several tobacco products removed from the predicate identified by the applicant. FDA would request this information when necessary to ensure that any order issued by the Agency complies with section 910(a)(2)(A)(i)(I) of the FD&C Act. Before requesting this information from the applicant, FDA would review other relevant SE Reports in the chain, for example, the first SE Report that received an SE order using the grandfathered product as a predicate product to make this finding. If FDA is unable to look back to data provided to the Agency regarding the grandfathered product and the applicant does not provide the information, FDA would be unable to make the finding required by section 910(a)(2)(A)(i)(I) of the FD&C Act. FDA encourages applicants to provide this information with the initial SE Report to support an efficient review of the SE Report, although FDA acknowledges this may be more difficult if the applicant is not the manufacturer or owner of the predicate tobacco product. FDA requests specific public comment on this proposed provision and any challenges it may present.

4. Amendments (Proposed § 1107.20)

Proposed § 1107.20(a) would permit an applicant to submit an amendment to an SE Report. Proposed § 1107.20(a) would require any applicant who chose to submit a health information summary with its SE Report under proposed § 1107.18(j)(1) to submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential and commercial information as defined in §§ 20.61 and 20.63 (21 CFR 20.61 and 20.63).

An applicant may not amend an SE Report to change the predicate tobacco product (proposed § 1107.20(b)). Because the comparison between the new and predicate tobacco products is the crux of the substantial equivalence determination, changing the predicate product changes the fundamental basis of the analysis. An applicant that determines that a predicate change is necessary should withdraw the initial SE Report and resubmit the SE Report with the information related to the new predicate tobacco product as described in proposed § 1107.18.

In addition, under proposed § 1107.20(c), an applicant may not amend a closed SE Report, *e.g.,* one that FDA has refused to accept, closed, canceled, or issued an order for under proposed § 1107.44, or one that has been withdrawn under proposed § 1107.22. Proposed § 1107.20(d) also explains that FDA would review the additional information in the next review cycle (proposed § 1107.42 discusses review cycles). As explained in proposed § 1107.62, SE Reports, including amendments, would be submitted to CTP's Document Control Center. Phone calls and emails to FDA staff would not be considered amendments to an SE Report.

5. Withdrawal by Applicant (Proposed § 1107.22)

Proposed § 1107.22 would permit an applicant to make a request to withdraw an SE Report unless FDA has closed the SE Report through an action in proposed § 1107.44 (all FDA actions in proposed § 1107.44 would close the SE

Report except for a request for additional information in proposed § 1107.44(b)). FDA has determined that withdrawal of an SE Report would benefit both the Agency and the applicant by potentially saving time and resources if the original SE Report might otherwise be insufficient or marketing authorization is no longer desired. The withdrawal request would state: (1) If the withdrawal is due to a health or safety concern related to the tobacco product; (2) the STN; and (3) the name of the new tobacco product that is the subject of the SE Report. This information would assist FDA in correctly identifying the SE Report to be withdrawn and also help inform FDA as to whether there were any concerns under section 909 of the FD&C Act (*e.g.,* relating to serious unexpected adverse experiences). Under proposed § 1107.22(b), an SE Report would be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn (see also proposed § 1107.40(e)).

The SE Report is an Agency record even if withdrawn. Thus, under proposed § 1107.22(c), FDA would retain the withdrawn SE Report consistent with Agency record retention schedules and policies and, under the Agency's public information regulations in part 20, would provide a copy to the applicant upon request subject to § 20.45. If the withdrawal request is made at the final review stage and FDA has identified unresolved deficiencies in the SE Report, FDA may provide a list of deficiencies in the communication that the Agency sends to the applicant acknowledging withdrawal. Under proposed § 1107.40(e), an SE Report would be considered withdrawn when FDA issues a notice stating that it is withdrawn.

6. Change in Ownership of an SE Report (Proposed § 1107.24)

Proposed § 1107.24 would reflect that transfers in ownership of SE Reports occur. This proposed section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of an SE Report. Proposed § 1107.24 applies to both pending SE Reports and SE Reports that are the subject of an SE order. Under proposed § 1107.24, at the time of the transfer, the new and former applicants (or owners) of the SE Report would be required to submit certain information to the Agency. First, the former applicant would be required to submit a notice to FDA identifying the new applicant and stating that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. Second, the new applicant would be required to submit a signed notice to FDA containing the following information:

- To the extent applicable, the new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report (*e.g.,* this could be an agreement by the new applicant to conduct studies the former applicant had agreed to conduct in support of a request for an extension of time to respond to a deficiency);
- The date that the change in ownership is effective;
- Either a statement that the new applicant has a complete copy of the SE Report that FDA determined was substantially equivalent (including any amendments, or any records required to be kept under proposed § 1107.58); or a statement of intent to request a copy of the SE Report under the Freedom of Information Act (FDA's implementing regulations are in part 20); and
- A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

Although FDA expects that the new applicant would have a copy of the SE Report from the former applicant, if the new applicant requests a copy of the SE Report from FDA, FDA would provide a copy to the new applicant, subject to the Freedom of Information Act requirements as implemented by FDA at part 20 and under the fee schedule in § 20.45.

The new applicant also would be required to make available all required records upon inspection by FDA (proposed § 1107.58 would impose a recordkeeping requirement). The information required to be made available for inspection would include raw data and other information necessary to substantiate the SE Report.

C. FDA Review (Proposed Subpart D)

1. Communications Between FDA and Applicants (Proposed § 1107.40)

Proposed § 1107.40 would establish general principles and provide clarity regarding communications between FDA and applicants during review of an SE Report. Proposed § 1107.40(a) explains that, during the course of FDA's review of an SE Report, FDA may seek to communicate with applicants about relevant matters, including scientific and procedural issues that arise during the review process. Communications regarding medical issues may arise if adverse events reports exist for the tobacco product. FDA may use a variety of methods to communicate with applicants, such as telephone conversations, letters, or emails, depending on the circumstances and issues. FDA would document any communications regarding an SE Report in accordance with 21 CFR 10.65.

Proposed § 1107.40(b) would provide that applicants and representatives of the Agency may have meetings to discuss scientific and other issues. Applicants interested in requesting meetings would direct their requests to the Office of Science through the Document Control Center. For further information, applicants may review the guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products'' (May 25, 2012, 77 FR 31368; revised guidance issued July 2016). As discussed in this guidance, FDA does not intend to grant meetings in most circumstances to discuss an applicant's questions related to a pending SE Report because the timing is frequently inappropriate (*e.g.,* premature or late, depending on stage of review) and such meetings are generally an inefficient or duplicative use of resources. For example, the applicant may be seeking substantive information while FDA's review is underway but before FDA has issued a deficiency letter or other response. Please note that each SE Report has a specific CTP contact to whom an applicant may ask clarifying questions, which helps ensure faster and more direct responses. FDA specifically requests public comment on the proposed decision to not grant meetings to discuss an applicant's questions related to a pending SE Report. Specifically, FDA seeks to understand if there are reasons why such meetings may be necessary for an applicant to respond to a deficiency letter or if the absence of such meetings present obstacles to the applicant in responding to deficiency letters.

Proposed § 1107.40(c) would provide that, upon receipt of an SE Report under proposed § 1107.18, FDA would either refuse to accept the SE Report or issue an acknowledgement letter. FDA requests comment on what a reasonable period of time would be within which such refusal to accept or acknowledgement of receipt letters should be issued.

Proposed § 1107.40(d) addresses FDA's notification of deficiencies in an SE Report submitted under proposed § 1107.18. FDA reviewers would make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and, if appropriate, the data needed to enable

the Agency's review. For example, a reviewer might inform the applicant that a signature is needed for a certification, that provided test results have last values cutoff or appear to have a typographical error, or that the SE Report is missing a reference for support. This communication is intended to give applicants an opportunity to correct deficiencies in the SE Report and to submit an amendment if needed.

Proposed § 1107.40(e) explains that an SE Report would be considered withdrawn when FDA issues a notice stating that it is withdrawn, which would ensure that FDA has received the withdrawal notification and that both FDA and the applicant now consider the SE Report as withdrawn.

FDA invites public comments on the following topics related to reasonable time periods to respond to a deficiency letter:

- Appropriate timelines for responding to a deficiency letter identifying missing information that is described in the final rule;
- Appropriate timelines for responding to a deficiency letter identifying missing information that requests additional information not described in the final rule;
- When requests for extensions of time to respond to a deficiency letter should be granted, and
- Whether or not deadlines to respond to deficiency letters should be tailored to the relative burden of the request.

2. Review Cycles (Proposed § 1107.42)

Proposed § 1107.42(a) would set forth the timeframe for FDA's initial review cycle. The ''initial review cycle'' would consist of the 90 calendar days following: (1) FDA's receipt of the SE Report and determination that a predicate product is grandfathered (for SE Reports that claim the predicate product was commercially marketed in the United States as of February 15, 2007, and FDA has not already determined the tobacco product is grandfathered) or (2) FDA's receipt of an SE Report (for SE Reports that contain a predicate product that was previously found substantially equivalent or for which FDA has previously determined that the predicate product is grandfathered). As described in more detail in proposed § 1107.44, FDA intends to review the SE Report and communicate with the applicant or take an action on an SE Report during this time period. At any time before FDA issues an order on the SE Report, the applicant would be allowed to withdraw it under proposed § 1107.22.

Proposed § 1107.42(b) would provide for the use of additional review cycles to complete FDA's review of an SE Report. If FDA issues a deficiency letter for an SE Report under proposed § 1107.40(d), FDA would stop reviewing the SE Report until it received a response to the notification of deficiencies (or deficiency letter) or the timeframe specified in the letter has elapsed. If the applicant fails to provide a response within the time period provided, FDA would issue an order denying marketing authorization for the new tobacco product under the criteria set forth in § 1107.48. If the applicant provides a response within the allotted timeframe, but FDA identifies the need for additional information as a result of this response, FDA could issue an additional deficiency notification. Each response would begin a new 90 calendar day review cycle for FDA to review the response.

FDA's intent is to complete review of an SE Report submitted under proposed § 1107.18 within a maximum of 270 review days (*i.e.,* three 90-day review cycles). Based on FDA's review experience, an SE Report should be resolved within three review cycles. If fewer review cycles are needed, FDA intends to decide in a shorter time period. Section 1107.40 would not obligate FDA to notify applicants of deficiencies in all circumstances before taking an action on an SE Report per proposed § 1107.44 or proposed § 1107.48. In any case where the SE Report has significant deficiencies, FDA might issue an order denying marketing authorization without providing additional opportunities to provide the missing information. Examples of significant deficiencies include when an SE Report provides no scientific evidence to substantiate a statement from the applicant that the new tobacco product does not raise different questions of public health or when an SE Report has multiple deficiencies but the applicant does not provide responses to all of the deficiencies. FDA requests public comment on whether FDA should provide specific timeframes within which applicants would need to respond to deficiency letters, along with an explanation as to why the proposed timeframes may be suitable for addressing the concerns commonly cited in the letters and why.

Proposed § 1107.42(c) states that, in the event that an applicant's response to FDA's deficiency notification(s) does not provide adequate information or the applicant provides information but the SE Report remains deficient, FDA intends to issue an order denying market authorization under the criteria set forth in proposed § 1107.48. The applicant also could make a written request to withdraw the SE Report under proposed § 1107.22 at any time before FDA issues an order regarding the SE Report.

3. FDA Action on an SE Report (Proposed § 1107.44)

Proposed § 1107.44 lists six actions FDA may take after completing review of an SE Report:

- First, FDA could refuse to accept the SE Report and not begin substantive scientific review if the SE Report does not comply with the requirements of proposed § 1107.18 (this action would stop the review clock and end the review cycle). For example, FDA could refuse to accept an SE Report that was not written in English as required under § 1107.18(b), or did not provide the information on product composition as required under § 1107.19(c)(1). Or, FDA could advise the applicant that the SE Report is not appropriate under chapter IX of the FD&C Act because the product does not meet the definition of a tobacco product under section 201(rr) of the FD&C Act.
- Second, FDA could request additional information as provided in proposed § 1107.40(d).
- Third, FDA could issue a letter closing the SE Report if it not possible to make a determination on an SE Report (sometimes referred to as an administrative closure, for example, which we might do when there is no way to determine if a new product is SE or NSE and additional information is unavailable);
- Fourth, FDA could issue a letter canceling the SE Report if FDA finds it mistakenly acknowledged the SE Report, *e.g.,* the SE Report does not pertain to a new tobacco product;
- Fifth, FDA could issue an order finding the new tobacco product to be substantially equivalent and in compliance with the requirements of the FD&C Act under proposed § 1107.46.
- Sixth, FDA could issue an order denying marketing authorization under proposed § 1107.48 (NSE order) because:
  - The applicant has failed to provide the information needed for FDA to find that the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed in the United States on February 15, 2007;
  - The new tobacco product is not substantially equivalent to a tobacco product that was commercially marketed in the United States on February 15, 2007; or

○ The new tobacco product is not in compliance with the requirements of the FD&C Act. For example, a new tobacco product is not in compliance with the requirements of the FD&C Act if the manufacturer of such product is in arrears with respect to its user fees; therefore, FDA would issue an NSE order.

4. Issuance of an Order Finding a New Tobacco Product Substantially Equivalent (Proposed § 1107.46)

Proposed § 1107.46 would explain that if, after review, FDA determines that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, and in compliance with the FD&C Act, the Agency would send the applicant an order authorizing the marketing of the product. The marketing authorization would be effective on the date the order is issued, which would typically be noted on the first page of the order.

5. Issuance of an Order Denying Marketing Authorization (Proposed § 1107.48)

Proposed § 1107.48(a) would provide that, in general, if FDA: (1) Is unable to determine that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, or (2) determines that the new tobacco product is not in compliance with the FD&C Act, the Agency would issue an NSE order indicating that the manufacturer cannot market the new tobacco product. FDA would communicate this decision to the applicant in writing. Proposed § 1107.48(b) provides that the NSE order would describe the basis for denying marketing authorization. FDA intends to describe any deficiencies that FDA has identified in an SE Report.

6. Rescission of Order (Proposed § 1107.50)

Proposed § 1107.50 would provide the procedural mechanism for FDA to rescind an SE order and describes the grounds for when an SE order may be rescinded. FDA intends to exercise this authority in a judicious and timely way in specific circumstances. FDA is proposing this provision based on our authority to issue an order only when it can make the findings provided in section 910(a)(2)(A)(i) of the FD&C Act and our authority to promulgate regulations for the efficient enforcement of the FD&C Act (section 701 of the FD&C Act). FDA's inherent authority to timely revisit and reconsider prior decisions is also supported by case law, with the inherent authority for timely administrative reconsideration premised on the notion that the '' 'power to reconsider is inherent in the power to decide.' '' *See Ivy Sports Med. LLC,* v. *Burwell,* 767 F.3d 81, 86 (D.C. Cir. 2014) (quoting *Albertson* v. *FCC,* 182 F.2d 397, 399 (D.C. Cir. 1950)). Where, as here, nothing in the Tobacco Control Act suggests that Congress intended to displace this inherent authority in the context of SE determinations, FDA may rescind an SE order based on its inherent authority. If, after issuing an SE order, FDA later determines, for example, that the order was based on false information or there was an error in information upon which the SE order is based, FDA would rescind the SE order. This proposed section would provide that—

- First, FDA may rescind an SE order if, after an order has issued, FDA becomes aware that the tobacco product for which the order has been issued:
  - ○ Does not have the same characteristics as the predicate tobacco product or
  - ○ has different characteristics and there is insufficient information demonstrating that it was not appropriate to require a premarket tobacco product application under section 910(b) of the FD&C Act because the product does not raise different questions of public health.
- Second, FDA may rescind an SE order if, after an order has issued, FDA becomes aware that the SE Report (including any submitted amendments) contains an untrue statement of material fact.
- Third, FDA may rescind an SE order if the SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent, and the predicate tobacco product relied on in the SE Report has been found ineligible because its SE Report (including any submitted amendments) contains an untrue statement of material fact, and/or a predicate product on which any of the previous substantial equivalence determinations was based, going back to the original grandfathered product, has been found ineligible because its SE Report (including any amendments) contained an untrue statement of material fact.
- Fourth, FDA may rescind an SE order if FDA or the applicant has removed from the market due to a health or safety concern related to the tobacco product:
  - ○ The predicate product on which the substantial equivalence determination is based and/or
  - ○ a predicate product on which any of the previous substantial equivalence determinations is based, going back to the original grandfathered product, if the SE Report compared the new tobacco product to a tobacco product that FDA previously found substantially equivalent. FDA may rescind in this scenario because the new tobacco product is SE to, or is in the same generational line as a predicate tobacco product with safety issues, and, therefore, may present similar safety concerns.

Proposed § 1107.50(b) states that, generally, FDA would rescind an SE order only after it has provided notice to the applicant and an opportunity for a hearing under part 16. FDA is proposing to amend § 16.1 to add a reference § 1107.50. FDA encourages applicants to bring errors to the Agency's attention that may necessitate rescission, and FDA intends to work with applicants in such scenarios.

In addition, FDA may need to rescind an order without providing notice and a prior opportunity for a hearing if FDA finds that the continued marketing of the tobacco product presents a serious risk to public health, *e.g.,* if the applicant represented that the new tobacco product conformed to a tobacco product standard, but FDA later determined that the new tobacco product did not conform to a tobacco product standard in a way that presents a serious risk to public health. Another example would be if FDA identifies data integrity issues during an inspection that would lead FDA to believe that the tobacco product presents a serious risk to public health. In these cases, FDA would provide the applicant an opportunity for a hearing as soon as possible after the rescission.

D. Miscellaneous (Proposed Subpart E)

Subpart E describes other procedures and requirements related to SE Reports, including record retention, electronic submission requirements, foreign data, and confidentiality considerations.

1. Record Retention (Proposed § 1107.58)

Consistent with the authority to require recordkeeping under section 909 of the FD&C Act, proposed § 1107.58, would require applicants receiving an order under proposed § 1107.46 authorizing the marketing of a new tobacco product to maintain all records supporting that SE Report for at least 4 years from the date of the order even if such product is discontinued. FDA has selected 4 years as a means to help ensure that the records would be available for at least one biennial FDA

inspection under section 704 and 905(g) of the FD&C Act. The records would be required to be legible, written in English or an English translation provided, and available for inspection and copying by officers or employees designated by the Secretary of Health and Human Services. Applicants that have stopped marketing a tobacco product may want to retain the records for a longer period, if the product might be reintroduced in order to avoid the time and expense of having to generate the information again.

2. Confidentiality (Proposed § 1107.60)

Proposed § 1107.60(a) states that FDA would determine the public availability of any part of any SE Report and other content related to an SE Report as provided under this proposed section and part 20 (Public Information). The Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as certain provisions of the FD&C Act, *e.g.,* section 301(j) (21 U.S.C. 331(j)) and section 906(c) (21 U.S.C. 387f(c)), govern the disclosure of the existence of a pending SE Report and the information contained in such an SE Report. Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure. One such provision, 5 U.S.C. 552(b)(4), exempts records that are ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'' from the requirement of mandatory disclosure. Part 20 of FDA's regulations sets forth FDA's general regulations concerning public availability of FDA records.

Like with drugs and devices, the intent to market a tobacco product is often considered confidential commercial information, as premature disclosure could result in a competitive advantage to competitors. Therefore, FDA is proposing § 1107.60(b)(1), which would address the confidentiality of an SE Report prior to the issuance of an order under either proposed § 1107.46 or proposed § 1107.48. Under the proposed regulation and consistent with part 20, FDA would not publicly disclose the existence of an SE Report unless the applicant has publicly disclosed or acknowledged the existence (as such disclosure is defined in § 20.81), or has authorized FDA in writing to publicly disclose or acknowledge, that the applicant has submitted the SE Report to FDA.

Proposed § 1107.60(b)(2) provides that FDA would not disclose the existence or contents of an FDA communication with an applicant regarding its SE Report except to the extent that the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, the existence of or contents of that particular FDA communication. Proposed § 1107.60(b)(3) provides that FDA would not disclose information contained in an SE Report unless the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information. If the applicant has publicly disclosed or acknowledged, or authorized FDA in writing to publicly disclose or acknowledge, that particular information contained in an SE Report, FDA may disclose that particular information.

Proposed § 1107.60(c) would address the disclosure of data and information after an order is issued under proposed § 1107.46. This proposed section would provide that, after an order under § 1107.46 (finding a new tobacco product substantially equivalent), FDA would make the following information related to the SE Report and order available for public disclosure upon request or at FDA's own initiative, including information from amendments to the SE Report and FDA's reviews of the SE Report: (1) All data previously disclosed to the public, as such disclosure is defined in § 20.81; (2) any protocol for a test or study, except to the extent it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61; (3) information and data submitted to demonstrate that the new tobacco product does not raise different questions of public health, except to the extent it is shown to fall within the exemptions established in § 20.61 for trade secrets and confidential commercial information, or in § 20.63 for personal privacy; (4) correspondence between FDA and the applicant, including any requests FDA made for additional information and responses to such requests, and all written summaries of oral discussions between FDA and the applicant, except to the extent it is shown to fall within the exemptions in § 20.61 for trade secrets and confidential commercial information, or in § 20.63 for personal privacy; and (5) the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to submit an environmental assessment under part 25 of this chapter.

Even after issuance of an order under § 1107.48 (Denying marketing authorization), the applicant's intent to market may still constitute confidential commercial information, as the applicant may still be planning to market the new tobacco product that is the subject of the SE Report (*e.g.,* by submitting a new SE Report, a PMTA, or a request for exemption from substantial equivalence, or by seeking further review of the denial). Therefore, proposed § 1107.60(d) addresses the disclosure of data and information after FDA issues an order under § 1107.48 (Denying marketing authorization). Under this proposed subsection, FDA may make certain information related to the SE Report and the order available for public disclosure upon request or at FDA's own initiative except to the extent the information is otherwise exempt from disclosure under part 20. Information FDA may disclose includes the tobacco product category (*e.g.,* cigarette), tobacco product subcategory (*e.g.,* filtered), package size, and the basis for the order denying marketing authorization.

Proposed § 1107.60(e) addresses disclosure of the health information summary or statement and would provide that health information required by section 910(a)(4) of the FD&C Act, if submitted as part of the SE Report (which includes any amendments), would be disclosed within 30 calendar days of issuing a substantially equivalent order. If the applicant has instead submitted a 910(a)(4) statement as provided in § 1107.18(j)(2), FDA would make publicly available on FDA's website the responsible official to whom a request for health information may be made. FDA intends to include this information on our website to ensure that the information is easily accessible to requestors.

3. Electronic Submission (Proposed § 1107.62)

Based on our authority in section 905 of the FD&C Act to prescribe the format of SE Reports, proposed § 1107.62(a) and (b) would require the applicant to submit the SE Report and supporting and other related documents in an electronic format that FDA can process, read, review, and archive unless a waiver from this requirement is requested by the applicant and FDA grants the waiver. Reasons that an applicant might request a waiver would include that the applicant has no access to email or a computer. Under proposed § 1107.62(c), an applicant that has a waiver would submit a paper submission to the address that FDA provides in the letter granting the waiver. FDA is proposing § 1107.62 based on FDA's general experiences with electronic submission, which FDA

has found helps facilitate premarket reviews because electronic submission typically has enabled FDA to receive, open, and read a submission more quickly than a submission submitted on paper through postal mail. If this rule is finalized, FDA intends to provide information on submitting information in an electronic format that FDA can process, read, review and archive (*e.g.,* method of transmission, media, file formats, preparation, organization of files, accompanying metadata) (*https://www.fda.gov/TobaccoProducts/default.htm*). FDA intends to update this information as needed (*e.g.,* to accommodate changes in technology).

IV. Other Issues for Consideration

In addition to comments and information on the proposed requirements described in section III, FDA is also seeking comments and information on whether some modifications to tobacco products that result in a new tobacco product, beyond those eligible for an exemption from substantial equivalence, might be handled through a ''categorical'' approach to substantial equivalence. Under such an approach, FDA would establish categories of modifications, and if a modification is within a category, the applicant could then submit a streamlined SE Report that identifies the modification and demonstrates substantial equivalence. FDA is soliciting concerns or benefits of this type of approach, along with information on the types of modifications or categories that might be handled in this way, or should not be handled this way.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting and recordkeeping. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Substantial Equivalence Reports for Tobacco Products.

Description: Tobacco Products, Substantial Equivalence Reports, Requirements for Submitting Information Needed to Determine Substantial Equivalence and Maintaining Records to Support a Substantial Equivalence Report.

This proposed rule would establish requirements for the content and format of substantial equivalence (SE) Reports (proposed §§ 1107.18 and 1107.19). Most of the proposed requirements would mirror current practices and recommendations related to the submission of SE Reports, including information related to part 25 (environmental considerations), but the rule would provide both applicants and FDA more certainty regarding the content and format the SE Reports. A health information summary or statement would continue to be required (section 910(a)(4) of the FD&C Act) and the health summary or response to a request would be required to be in the format of a redacted SE Report, along with any additional health information about the new tobacco product, including any information, research, or data about adverse health effects, that the applicant has or knows about and that is not contained in the SE Report.

As is currently the practice, the proposed rule would continue to permit amendments for SE Reports submitted under proposed § 1107.18, *e.g.,* to address deficiencies (proposed § 1107.20). Also in accordance with current practice, the proposed rule would continue to permit withdrawals (proposed § 1107.22) of pending SE Reports. The proposed rule would also propose requirements for when the ownership of an SE Report changes to ensure that FDA has information related to the current applicant (proposed § 1107.24).

The proposed rule would establish a recordkeeping requirement, under which applicants would be required to maintain records supporting the SE Report for an authorized new tobacco product for 4 years from the date of an order finding substantial equivalence, even if such product is discontinued (proposed § 1107.58).

The proposed rule would require that respondents submit an SE Report in an electronic format, unless a waiver from this requirement is requested by the applicant and granted by FDA (proposed § 1107.62). FDA created two new forms for submission; Form FDA 3964, Tobacco Amendment and General Correspondence; and Form FDA 3965, Tobacco Substantial Equivalence Report Submission.

Description of Respondents: Manufacturers of tobacco products who submit SE Reports.

Existing Burden OMB Control Number 0910–0673

TABLE 9—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	410	1	410	300	123,000
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	250	1	250	90	22,500
Product Quantity Change SE Report	264	1	264	87	22,968
Product Quantity Change Bundled SE Report	55	1	55	62	3,410
Totals					171,878

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This chart represents the currently OMB approved burden for the SE program.

Reporting Burden Updated Estimates

TABLE 10—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					278,637

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Draft burden not yet OMB approved.

In the **Federal Register** of September 6, 2018 (83 FR 45251), FDA published a notice soliciting comments on the extension of the current SE program. The numbers above in table 10 represent the tentative revisions which have not yet been approved by OMB. These estimates revise the number of reports under OMB control number 0910–0673 and take into account updated registration and listing data. The previous estimate for reports was 979 and total burden hours were 171,878. This chart accounts for the tentative increase in burden due to the expected rise in submissions other than any increases in burden due to the proposed rule, if finalized.

New Reporting Per Rule

TABLE 11—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3965 Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence	628	1	628	.083	52
Waiver from Electronic submission 1107.62(b)	240	1	240	.25	60
Totals					897

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Draft burden not yet OMB approved.

Final Combined Reporting Burden (Tables 10 +11)

TABLE 12—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SE Report 1107.18	683	1	683	300	204,900
Bundled SE 1107.18	456	1	456	90	41,040
SE Report where applicant provides certification for identical characteristics 1107.18(g) and 1107.18(1)(2)	239	1	239	87	20,793
SE Report where applicant provides certification for some identical characteristics (bundled) 1107.18(g) and 1107.18(1)(2)	192	1	192	62	11,904
FDA 3965 Tobacco Substantial Equivalence Report Submission	1,570	1	1,570	.5	785
FDA 3964 Tobacco Amendment and General Correspondence Report	628	1	628	.083	52
Waiver from Electronic submission 1107.62(b)	240	1	240	.25	60
Totals					279,534

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Draft burden not yet OMB approved.

New Final Recordkeeping Burden

TABLE 13—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping SE Report under 1107.18 1107.58	471	1	471	2.5	1,178

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Draft burden not yet OMB approved.

FDA's estimates are based on experience with SE Reports, registration and listing data, interactions with the industry, and information related to other regulated products. As explained above, taking into account the updated registration and listing data for deemed tobacco products, the estimated annual number of SE Reports is expected to be 1,570. That estimate is not expected to change as a result of the proposed rule, if finalized.

When groups of full SE Reports or SE Reports that each contain a certification that some characteristics are identical have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the substantial equivalence pathway to market their products. Table 9 describes the annual reporting burden for compliance with the requirements to demonstrate substantial equivalence under the FD&C Act. We do not expect a large burden increase for this program, as, without the proposed rule, manufacturers would routinely submit SE Reports for new tobacco products, and the Agency believes most respondents are currently practicing most of the proposed requirements. FDA will revise this collection with the new burden. FDA requests public comments on the estimated burden associated with the requirements associated with this rule and whether there is any evidence, information, or data to support alternate burden estimates.

Table 11 describes the annual reporting burden as a result of the requirements proposed in §§ 1107.18 and 1107.19, implementing the substantial equivalence requirements of section 905(j)(1)(A)(i) and 910(a) of the FD&C Act. This proposed rule would require manufacturers to submit SE Reports electronically (proposed § 1107.62). We estimate that it would initially take about 30 minutes per product to fill out the Form FDA 3965. However, for amendments we estimate that filling out the Form FDA 3964 will take 5 minutes as applicants can copy and paste from the first submission. Proposed 1107.62(b) also allows for waivers from the electronic format requirement. FDA estimates that 240 respondents or 15 percent of SE Reports (1,570) will submit a waiver.

Based on updated information, FDA estimates that it will receive 683 full initial SE Reports for a new tobacco product each year under proposed § 1107.18 that take a manufacturer approximately 300 hours to prepare. Additionally, manufacturers may bundle groups of SE Reports for their new products in the same product category and subcategory where the proposed modifications are the same; when a group of similar SE Reports are bundled, the reporting burden for the initial SE Report is expected to take the same amount of time as a stand-alone SE Report. However, the reporting burden for subsequent bundled SE Reports is expected to be lower than the initial SE Report. We expect to receive 456 bundled SE Reports under proposed § 1107.18 (other than the initial SE Report in the bundle) at approximately 90 hours per response for a total of 41,040 hours.

In the absence of more specific information concerning SE Reports where applicants provide a certification for some identical characteristics under proposed § 1107.18(g) and 1107.18(l)(2), FDA estimates receiving 239 such SE Reports at 87 hours per response for a total of 20,973 hours. We also estimate receiving 192 bundled SE Reports where applicants provide a certification for some identical characteristics under proposed §§ 1107.18(g) and 1107.18(*l*)(2) (other than the initial SE Report in the bundle) at 62 hours per response for a total of 11,904 hours. Although we believe that the number of SE Reports that include a certification will increase because the proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product, in the absence of specific information on how many more applicants might choose to certify, we are maintaining our previous estimates at this time. We request comment on these estimates.

FDA has based these estimates on the full analysis of economic impacts and experience with the recently-revised existing information collection that applies to tobacco products. In addition, anyone submitting an SE Report is required to submit an environmental assessment prepared in accordance with § 25.40 under proposed § 1107.18(k). The burden for environmental reports has been included in the burden per response for each type of SE Report.

Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours preparing an environmental assessment for a full SE Report under proposed § 1107.18.

Generally, an applicant may withdraw its SE Report after submission (proposed § 1107.22), change the ownership of its SE Report (proposed § 1107.24), and amend its SE Report (proposed § 1107.20). The information required to grant these requests is already being collected, so we do not expect a change in burden.

FDA estimates that 30 percent of SE Reports or 471 respondents will maintain required records related to their SE Reports at 2.5 hours per record for a total of 1,178 recordkeeping hours.

FDA estimates that the burden for new requirements will increase this collection by 108,834 (107,656 + 1,178 recordkeeping). The burden for the submission of substantial equivalence information is estimated to total 280,712 hours (279,534 reporting and 1,178 recordkeeping). This proposed rule also refers to previously approved collections of information found in FDA regulations. Proposed § 1107.40 references meetings that may be held with applicants who want to meet with FDA to discuss scientific and other issues. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance entitled ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' The collections of information in the guidance referenced have been approved under OMB control number

0910–0731. In addition to the premarket application under section 910(b) and a report under 905(j)(1)(A)(i), certain new tobacco products may use the exemption premarket pathway, see 21 CFR 1107.1. The collections of information found in 21 CFR 1107.1 have been approved under OMB control number 0910–0684.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. Executive Order 13132: Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) is an express preemption provision. Section 916(a)(2) provides that ''no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to . . . premarket review.'' Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 916(a)(2) of the FD&C Act.

VII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist to indicate that the specific proposed action may significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have determined that the compliance costs are less than 0.1 percent of revenues, we propose to certify that the rule would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports. We estimate that the present value of industry compliance costs ranges from $0.60 million to $2.64 million, with a primary estimate of $1.61 million at a 3 percent discount rate, and from $0.56 million to $2.32 million, with a primary estimate of $1.43 million at a 7 percent discount rate over 10 years. Annualized industry compliance costs over 10 years range from $0.07 million to $0.31 million, with a primary estimate of $0.19 million at a 3 percent discount rate and from $0.08 million to $0.33 million, with a primary estimate of $0.20 million at a 7 percent discount rate.

The benefits of this proposed rule are potential time-savings to industry and cost-savings to government. This proposed rule clarifies when applicants may certify that certain characteristics are identical in the new tobacco product and the predicate tobacco product. Certifying may save applicants time in preparing their SE Reports. In this proposed rule, we intend to shorten review times for SE Reports. In addition, based on our experience with prior SE Reports, we believe this proposed rule would lead to better SE Reports, saving us time in review and requiring fewer staff to review SE Reports, which would result in cost-savings. We estimate that the present value of government cost-savings ranges from $15 million to $198 million at a 3 percent discount rate, and from $12 million to $163 million at a 7 percent discount rate over 10 years. Annualized government cost-savings over 10 years range from $1.7 million to $23.2 million at both 3 and 7 percent discount rates.

The qualitative benefits of this proposed rule include additional clarity to industry about the requirements for the content and format of SE Reports. The proposed rule would also establish the general procedures we intend to follow in reviewing and communicating with applicants. In addition, this proposed rule would make the SE pathway more predictable.

The proposed rule's costs and benefits are summarized in Table 14 entitled ''Economic Data: Costs and Benefits Statement.''

TABLE 14—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Low estimate	Primary estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized	1.7	7.2	23.2	2016	7	10	Cost-savings to government.
$millions/year.	1.7	7.2	23.2	2016	3	10	Cost-savings to government.
Annualized				2016	7	10	
Quantified				2016	3	10	
Qualitative							Greater certainty for SE applicants.
Costs:							
Annualized Monetized	0.08	0.20	0.33	2016	7	10	
$millions/year.	0.07	0.19	0.31	2016	3	10	
Annualized				2016	7	10	
Quantified				2016	3	10	
Qualitative.							
Transfers:							
Federal Annualized Monetized $millions/year.				2016	7	10	
				2016	3	10	
	From:			To:			
Other Annualized Monetized $millions/year.				2016	7	10	
				2016	3	10	
	From:			To:			

Effects:
State, Local or Tribal Government: No effect
Small Business: No effect
Wages: No effect
Growth: No effect

In line with Executive Order 13771, in Table 15 we estimate present and annualized values of costs and cost-savings over an infinite time horizon. Our primary estimate of the present value over an infinite time horizon of net costs due to this proposed rule is −$101.4 million at a 7 percent discount rate, and −$237.7 million at a 3 percent discount rate. Our primary estimate of the annualized net costs is −$7.1 million at a 7 percent discount rate and −$7.1 million at a 3 percent discount rate. Table 15 summarizes the costs, cost-savings and net costs of this proposed rule. Based on these cost-savings this proposed rule, if finalized, would be considered a deregulatory action under E.O. 13771.

TABLE 15—E.O. 13771 SUMMARY TABLE

[In $ Millions 2016 dollars, over infinite time horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$2.05	$0.57	$3.56	$3.75	$0.69	$6.92
Present Value of Cost Savings	103.49	24.84	331.18	241.48	57.96	772.75
Present Value of Net Costs	(101.4)	(24.3)	(327.6)	(237.7)	(57.3)	(765.8)
Annualized Costs	0.14	0.04	0.25	0.11	0.02	0.21
Annualized Cost Savings	7.24	1.74	23.18	7.24	1.74	23.18
Annualized Net Costs	(7.1)	(1.7)	(22.9)	(7.1)	(1.7)	(23.0)

Note: Values in parentheses denote net negative costs (*i.e.,* cost-savings).

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 54) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Wayne, G. F. and G. N. Connolly, ''Application, Function, and Effects of Menthol in Cigarettes: A Survey of Tobacco Industry Documents,'' *Nicotine & Tobacco Research,* 6(Suppl. 1):S43–S54, 2004.
2. Brunnemann, K. D., J. C. Scott, and D. Hoffmann, ''N-Nitrosomorpholine and

Other Volatile N-nitrosamines in Snuff Tobacco,'' *Carcinogenesis,* 3(6):693–696, 1982.
3. Draft Form FDA 3965 (Substantial Equivalence Submission).
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54. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Content and Format of Substantial Equivalence Reports; Proposed Rule.

XI. Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1107

Administrative practice and procedure, Smoke, Smoking, Tobacco, Tobacco products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. In § 16.1(b)(2) add in numerical sequence an entry for ''§ 1107.50'' to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

* * * * *

PART 1107—EXEMPTIONS AND SUBSTANTIAL EQUIVALENCE REPORTS

■ 3. The authority citation for part 1107 is revised to read as follows:

Authority: 21 U.S.C. 371, 374, 387b, 387c, 387e(j), 387i, and 387j.

■ 4. The heading of part 1107 is revised to read as set forth above.

■ 5. Add subparts B through E to read as follows:

Subpart B—General

Sec.

Subpart C—Substantial Equivalence Reports

Subpart D—FDA Review

Subpart E—Miscellaneous

Subpart B—General

§ 1107.10 Scope.

(a) Subparts B through E of this part apply to a substantial equivalence report (or SE Report) for a new tobacco product that has:

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

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

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

§ 1107.12 Definitions.

For purposes of this part:

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

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

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

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

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

Additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating,

packaging, transporting, or holding), except that the term does not include tobacco or a pesticide chemical residue in or on raw tobacco, or a pesticide chemical.

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

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

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

Commercial distribution means any distribution of a tobacco product to consumers or to another person through sale or otherwise, but does not include interplant transfers of a tobacco product between registered establishments within the same parent, subsidiary, and/or affiliate company, nor does it include providing a tobacco product for product testing where such product is not made available for consumption or resale. ''Commercial distribution'' does not include the handing or transfer of a tobacco product from one consumer to another for personal consumption. For foreign establishments, the term ''commercial distribution'' has the same meaning, except that it does not include distribution of a tobacco product that is neither imported nor offered for import into 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 from a tobacco product, or any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the tobacco product to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

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

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

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

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

Grandfathered tobacco product means a tobacco product that was commercially marketed in the United States as of February 15, 2007, and does not include a tobacco product exclusively in test markets as of that date. A grandfathered tobacco product is not subject to the premarket requirements of section 910 of the Federal Food, Drug, and Cosmetic Act.

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

(1) Is or potentially is inhaled, ingested, or absorbed into the body; and

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

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

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

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

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

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

New tobacco product means:

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

(2) Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

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

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

Predicate tobacco product means a tobacco product that is a grandfathered tobacco product or a tobacco product that FDA has previously found substantially equivalent under section 910(a)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act.

Submission tracking number or *STN* means the number that FDA assigns to submissions that are received from a manufacturer of tobacco products, such as SE Reports and requests for grandfather determinations.

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

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

(2) Has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate

to require premarket review under section 910(b) and (c) of the Federal Food, Drug, and Cosmetic Act because the new tobacco product does not raise different questions of public health.

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

Tobacco product means any product made or derived from tobacco 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)), or a combination product (section 503(g)).

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.

Subpart C—Substantial Equivalence Reports

§ 1107.16 Submission of a substantial equivalence report.

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

§ 1107.18 Required content and format of a SE report.

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

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

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

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

(4) Predicate tobacco product description (as described in paragraph (f) of this section), including a statement that the predicate tobacco product has not been removed from the market at the initiative of FDA and has not been determined by judicial order to be adulterated or misbranded, and the submission tracking number of the SE order finding the predicate product SE, or the submission tracking number of, or information to support, a grandfathered determination of the predicate tobacco product;

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

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

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

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

(9) Compliance with 21 CFR part 25 (as described in paragraph (k) of this section); and

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

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

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

(1) The date the SE Report is submitted;

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

(3) FDA STN if previously assigned;

(4) Any other relevant FDA STN, such as a request for grandfathered determination or SE Report previously found substantially equivalent (if applicable), and cross-references to meetings with FDA regarding the new tobacco product;

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

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

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

(i) Manufacturer;

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

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

Tobacco product category:	Tobacco product subcategory:	Product properties:
(*A*)Cigarettes	(*1*) Combusted, Filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89 millimeters (mm), 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm).

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Combusted, Non-filtered	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Combusted, Other	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Non-Combusted (*e.g.,* a cigarette where the tobacco is heated not burned).	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 cigarettes, 25 cigarettes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing Flavor(s) (*e.g.,* none, menthol). —Source of energy (*e.g.,* charcoal, electrical heater). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Cigarette, Co-Package	For a new co-packaged tobacco product composed of multiple cigarette tobacco products, include, as applicable, all properties for each individual tobacco product, as identified in this section.
(B) Roll-Your-Own Tobacco Products.	(*1*) Roll-Your-Own Tobacco Filler ..	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 40 g). —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.,* bag, box, booklet). —Product quantity (*e.g.,* 50 sheets, 200 papers). —Length (*e.g.,* 79 mm, 100 mm, 110 mm). —Width (*e.g.,* 28 mm, 33 mm, 45 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Filtered Cigarette Tube	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Non-Filtered Cigarette Tube	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 tubes, 200 tubes). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Filter	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 100 filters, 200 filters). —Length (*e.g.,* 8 mm, 12 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Paper Tip	—Package type (*e.g.,* bag, box). —Product quantity (*e.g.,* 200 tips, 275 tips). —Length (*e.g.,* 12 mm, 15 mm). —Width (*e.g.,* 27 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

Tobacco product category:	Tobacco product subcategory:	Product properties:
	(*7*) Roll-Your-Own Co-Package	—For a new co-packaged tobacco product composed of multiple RYO tobacco products, include, as applicable, all properties for each individual tobacco product (*e.g.,* roll-your own tobacco, rolling paper, filtered cigarette tube, non-filtered cigarette tube, filter, paper tip) as identified in this section.
	(*8*) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product.
(C) Smokeless Tobacco Products ..	(*1*) Loose Moist Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 grams (g), 2 ounces). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Portioned Moist	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 2 g/piece). —Portion length (*e.g.,* 15 mm, 20 mm). —Portion width (*e.g.,* 10 mm, 15 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Snuff	
	(*4*) Loose Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2 ounces). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Portioned Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 pouches, 20 pieces). —Portion mass (*e.g.,* 1.5 g/pouch, 2 g/piece). —Portion length (*e.g.,* 15 mm, 20 mm). —Portion width (*e.g.,* 10 mm, 15 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Tobacco cut size (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Loose Dry Snuff	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g, 2 ounces). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*7*) Dissolvable	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 22.5 g, 20 g). —Portion count (*e.g.,* 15 sticks, 20 tablets). —Portion mass (*e.g.,* 1.5 g/strip, 1 g/piece). —Portion length (*e.g.,* 10 mm, 15 mm). —Portion width (*e.g.,* 5 mm, 8 mm). —Portion thickness (*e.g.,* 3 mm, 4 mm). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*8*) Loose Chewing Tobacco	—Package type (*e.g.,* bag, pouch, wrapped). —Product quantity (*e.g.,* 20 g, 3 ounces). —Tobacco cut size (*e.g.,* 0.05 mm, 0.07 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).

Tobacco product category:	Tobacco product subcategory:	Product properties:
	(*9*) Portioned Chewing Tobacco	—Package type (*e.g.,* plastic can with metal lid, plastic can with plastic lid). —Product quantity (*e.g.,* 20 g). —Portion count (*e.g.,* 10 bits). —Portion mass (*e.g.,* 2 g/bit). —Portion length (*e.g.,* 8 mm, 10 mm). —Portion width (*e.g.,* 6 mm, 8 mm). —Portion thickness (*e.g.,* 5 mm, 7 mm). —Characterizing flavor(s) (*e.g.,* none, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*10*) Smokeless Co-Package	—For a new co-packaged tobacco product composed of multiple smokeless tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.
	(*11*) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
(D) ENDS (Electronic Nicotine Delivery System).	(*1*) Open E-Liquid	—Package type (*e.g.,* bottle, box). —Product quantity (*e.g.,* 1 bottle, 5 bottles). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (*e.g.,* 10 milliliters (ml)). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Closed E-Liquid	—Package type (*e.g.,* cartridge). —Product quantity (*e.g.,* 1 cartridge, 5 cartridges). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —E-liquid volume (*e.g.,* 10 ml). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Closed E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 6 mm, 8 mm). —E-liquid volume (*e.g.,* 2 ml, 5 ml). —Nicotine concentration (*e.g.,* 0, 0.2 mg/ml). —PG/VG ratio (*e.g.,* N/A, 0/100, 50/50). —Wattage (*e.g.,* 100 W, 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —Additional properties needed to uniquely identify the tobacco product.
	(*4*) Open E-Cigarette	—Package type (*e.g.,* box, none, plastic clamshell). —Product quantity (*e.g.,* 1 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Length (*e.g.,* 100 mm, 120 mm). —Diameter (*e.g.,* 8 mm, 14 mm). —E-liquid volume (*e.g.,* 2 ml, 5 ml). —Wattage (*e.g.,* 100 Watts (W), 200 W). —Battery capacity (*e.g.,* 100 mAh, 200 mAh). —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 e-cigarette, 5 e-cigarettes). —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry, wintergreen). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) ENDS Co-Package	—For a new co-packaged tobacco product composed of multiple ENDS tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.
	(*7*) ENDS Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol, cherry).

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Additional properties needed to uniquely identify the tobacco product.
(E) Cigars	(*1*) Filtered, Sheet-Wrapped Cigar	—Package type (*e.g.,* hard pack, soft pack, clam shell). —Product quantity (*e.g.,* 20 filtered cigars, 25 filtered cigars). —Characterizing flavor (*e.g.,* none, menthol). —Length (*e.g.,* 89 mm, 100 mm). —Diameter (*e.g.,* 6 mm, 8.1 mm). —Ventilation (*e.g.,* none, 10%, 25%). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Unfiltered, Sheet-Wrapped Cigar.	—Package type (*e.g.,* box, film sleeve). —Product quantity (*e.g.,* 1 cigar, 5 cigarillos). —Characterizing flavor (*e.g.,* none, menthol). —Length (*e.g.,* 100 mm, 140 mm). —Diameter (*e.g.,* 8 mm, 10 mm). —Tip (*e.g.,* none, wood tips, plastic tips). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*3*) Leaf-Wrapped Cigar	—Package type (*e.g.,* box, film, sleeve, none). —Product quantity (*e.g.,* 1 cigar, 5 cigars). —Characterizing flavor (*e.g.,* none, whiskey). —Length (*e.g.,* 150 mm, 200 mm). —Diameter (*e.g.,* 8 mm, 10 mm). —Wrapper material (*e.g.,* burley tobacco leaf, Connecticut shade grown tobacco leaf). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Cigar Component	—Package type (*e.g.,* box, booklet). —Product quantity (*e.g.,* 10 wrappers, 20 leaves). —Characterizing flavor (*e.g.,* none, menthol, cherry). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Cigar Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —Characterizing flavor (*e.g.,* none, tobacco, menthol, cherry). —Tobacco cut size (*e.g.,* 5 mm, 10 mm). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*6*) Cigar Co-Package	—For a new co-packaged tobacco product composed of multiple cigar tobacco products, include, as applicable, all properties for each individual tobacco product as identified previously.
	(*7*) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product.
(F) Pipe Tobacco Products	(*1*) Pipe	—Package type (*e.g.,* box, none). —Product quantity (*e.g.,* 1 pipe). —Length (*e.g.,* 200 mm, 300 mm). —Diameter (*e.g.,* 25 mm). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Pipe Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —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.,* bowl, shank, stem, screen, filter). —Product quantity (*e.g.,* 1 bowl, 1 stem, 100 filters). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*4*) Pipe Co-Package	—For a new co-packaged tobacco product composed of multiple pipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified previously.
	(*5*) Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —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). —Length (*e.g.,* 200 mm, 500 mm).

Tobacco product category:	Tobacco product subcategory:	Product properties:
		—Width (*e.g.,* 100 mm, 300 mm). —Number of hoses (*e.g.,* 1, 2, 4). —Characterizing flavor(s) (*e.g.,* none, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*2*) Waterpipe Tobacco Filler	—Package type (*e.g.,* bag, pouch). —Product quantity (*e.g.,* 20 g, 16 ounces). —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 g, 680 g). —Characterizing flavor(s) (*e.g.,* none, menthol, apple). —Portion count(*e.g.,* 20 fingers, 10 discs, 1 base). —Portion mass (*e.g.,* 15 g/finger). —Portion length (*e.g.,* 40 mm, 100 mm). —Portion width (*e.g.,* 10 mm, 40 mm). —Portion thickness (*e.g.,* 10 mm, 40 mm). —Source of energy (*e.g.,* charcoal, battery, electrical). —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, apple). —Additional properties needed to uniquely identify the tobacco product (if applicable).
	(*5*) Waterpipe Co-Package	—For a new co-packaged tobacco product composed of multiple waterpipe tobacco products, include, as applicable, all properties for each individual tobacco product as identified in this section.
	(*6*) Waterpipe Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).
Other	Other	—Package type (*e.g.,* bag, box). —Product quantity. —Characterizing flavor(s) (*e.g.,* none, tobacco, menthol). —Additional properties needed to uniquely identify the tobacco product (if applicable).

(8) Address and the FDA Establishment Identifier (FEI) number(s) of the establishments involved in the manufacture and/or importation of the new and predicate tobacco products.

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

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

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

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

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

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

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

(3) A concise overview of the process used to manufacture the new tobacco product, including the fermentation process, where applicable, with information on the type and quantity of the microbial inoculum and/or fermentation solutions. If the manufacturing process for the new tobacco product does not affect the characteristics of the new tobacco product beyond what is described elsewhere in the SE Report, an applicant must state that to satisfy this provision.

(f) *Description of predicate tobacco product.* (1) The applicant must identify a predicate tobacco product that is either a grandfathered tobacco product or a tobacco product that FDA previously found to be substantially equivalent.

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

(i) Be in the same category and subcategory of product as the new tobacco product;

(ii) Have been either:

(A) Commercially marketed (not exclusively in a test market) in the United States as of February 15, 2007, as shown by either specific information sufficient to support this in the SE Report, including a statement that ''I, (name of responsible official), confirm that the predicate tobacco product, (insert name of predicate tobacco product), was commercially marketed

other than for test marketing as of February 15, 2007'', or reference to an STN for a previous determination by FDA that the predicate product is grandfathered; or

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

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

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

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

(g) *Comparison information.* The SE Report must include a comparison of the characteristics of the new tobacco product and the predicate tobacco product, as described in § 1107.19. If the new tobacco product has limited changes to a characteristic(s) when compared to the predicate tobacco product, and all other characteristics are identical (*e.g.,* a change to product quantity), the applicant must provide comparison information related to such characteristic(s), but may certify that the other characteristics identical under paragraph (1)(2) of this section. The applicant must maintain records supporting the certification consistent with § 1107.58.

(h) *Comparative testing information.* Other than for characteristics that are identical, and for which the applicant has certified that the characteristics are identical under paragraph (1)(2) of this section, the SE Report must provide comparative testing information on the characteristics of the new and predicate tobacco products, as described in § 1107.19, except where the applicant adequately justifies that such comparative testing information is not necessary to demonstrate that the new product has the same characteristics as the predicate or does not raise different questions of public health. The testing information must:

(1) Include the test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results);

(2) Be conducted on a sufficient sample size and on test samples that reflect the finished tobacco product composition and design;

(3) State whether the same test methods were used for the new tobacco product and the predicate product, and if the methods differed, an explanation as to how the results of the different test methods can be compared; and

(4) Identify national and international standards used to test the new and predicate tobacco products and explain any deviations from the standard, or state that no standards were used for the testing.

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

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

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

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

(1) *Health information summary.* If including a health information summary with the SE Report, the applicant must provide a copy of the full SE Report that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter (21 CFR 20.61 and 20.63); and either

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

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

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

(3) *Content of health information.* The health information the applicant agrees to make available in paragraph (j)(2) of this section must be a copy of the full SE Report, excluding all research subject identifiers, trade secrets, and confidential commercial information, as defined in 21 CFR 20.61 and 21 CFR 20.63; and either.

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

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

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

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

(k) *Compliance with 21 CFR part 25.* (1) The SE Report must include an environmental assessment prepared in accordance with § 25.40 of this chapter, or a valid claim of categorical exclusion. If the applicant believes that the action qualifies for an available categorical exclusion, the applicant must state under § 25.15(a) and (d) of this chapter that the action requested qualifies for a categorical exclusion, citing the particular exclusion that is claimed, and that to the applicant's knowledge, no extraordinary circumstances exist under § 25.21.

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

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

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

§ 1107.19 Comparison information.

The SE Report must include a comparison of the characteristics of the new tobacco product to the predicate tobacco product. The comparison section of the SE Report must be organized in the following manner:

(a) *Comparison of product design.* The SE Report must include descriptions of the product designs of the new and predicate tobacco products and identify any differences. The SE Report must include, in a tabular format, a side-by-side comparison of each design parameter of the new and predicate tobacco products. For each design parameter, the target value and range of acceptable values, actual measured value (where applicable), and range of measured values (where applicable) with units of measure must be provided. In addition, for each applicable design parameter, test data must be provided.

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

TABLE 1 TO § 1107.19(a)(1)

Provide target specification with upper and lower range limits for:	Provide test data (include test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for:
—Cigarette length (mm)	—Puff count
—Cigarette circumference (mm)	—Cigarette draw resistance (mm H_2O)
—Cigarette draw resistance (mm H_2O)	—Tobacco filler mass (mg)
—Tobacco filler mass (mg)	—Tobacco moisture (%)
—Tobacco rod density (g/cubic centimeter (cm_3))	—Filter ventilation (%)
—Tobacco moisture (%)	—Cigarette paper base paper basis weight (g/m_2))
—Filter ventilation (%)	—Cigarette paper base paper porosity (CU)
—Tipping paper length (mm)	—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* denier per filament, total denier, and filter density))
—Cigarette paper base paper basis weight (g/m_2)	—Filter pressure drop (mm H_2O)
—Cigarette paper base paper porosity (CU)	
—Cigarette paper band width (mm)	
—Cigarette paper band space (mm)	
—Filter efficiency (%) (If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (*e.g.,* denier per filament, total denier, and filter density))	
—Filter length (mm)	
—Filter pressure drop (mm H_2O)	

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

TABLE 2 TO § 1107.19(a)(2)

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) —Tobacco moisture (%) —Portion length (mm) (if applicable) —Portion width (mm) (if applicable) —Portion mass (mg) (if applicable) Portion thickness (mm) (if applicable) Pouch paper wicking Pouch paper porosity (CU) Pouch paper basis weight (g/m_2)	—Tobacco cut size (mm). —Tobacco moisture (%). —Portion mass (mg) (if applicable). —Pouch paper porosity (CU). —Pouch paper basis weight (g/m_2).
Nonportioned Smokeless Tobacco Products	
—Tobacco cut size (mm) —Tobacco moisture (%)	—Tobacco cut size (mm). —Tobacco moisture (%).

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

TABLE 3 TO § 1107.19(a)(3)

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:
—Paper length(mm) —Paper width (mm) —Mass per paper (mg) —Cigarette paper base paper basis weight (g/m_2) —Cigarette paper base paper porosity (CU) —Cigarette paper band porosity (CU) (if applicable) —Cigarette paper band width (mm) (if applicable) —Cigarette paper band space (mm) (applicable)	—Mass per paper (mg). —Cigarette paper base paper basis weight (g/m_2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU) (if applicable).

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

TABLE 4 TO § 1107.19(a)(4)

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 length (mm) —Tube circumference (mm) —Total mass (mg) —Cigarette paper base paper basis weight (g/m_2) —Cigarette paper base paper porosity (CU) —Cigarette paper band porosity (CU) —Cigarette paper band width (mm) —Cigarette paper band space (mm)	—Total mass (mg). —Cigarette paper base paper basis weight (g/m_2). —Cigarette paper base paper porosity (CU). —Cigarette paper band porosity (CU).

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

TABLE 5 TO § 1107.19(a)(5)

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 length (mm) —Tube circumference (mm) —Total mass (mg) —Tipping paper length (mm)	—Total mass (mg). —Filter ventilation (%). —Cigarette paper base paper basis weight (g/m_2). —Cigarette paper base paper porosity (CU).

TABLE 5 TO § 1107.19(a)(5)—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:
—Filter ventilation (%) —Cigarette paper base paper basis weight (g/m_2) —Cigarette paper base paper porosity (CU) —Cigarette paper band porosity (CU) —Cigarette paper band width (mm) —Cigarette paper band space (mm) —Filter length (mm) —Filter denier per filament (DPF) —Filter total denier (g/9000m) —Filter density (g/cm_3) —Filter pressure drop (mm H_2O)	—Cigarette paper band porosity (CU). —Filter denier per filament (DPF). —Filter total denier (g/9000m). —Filter density (g/cm_3). —Filter pressure drop (mm H_2O).

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

TABLE 6 TO § 1107.19(a)(6)

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 filler mass (mg) —Tobacco size (mm) —Tobacco moisture (%)	—Tobacco filler mass (mg). —Tobacco size (mm). —Tobacco moisture (%).

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

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

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

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

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

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

(iv) The function of the material;

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

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

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

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

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

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

(iii) The function of the ingredient;

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

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

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

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

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

(i) The type, including grade and variety;

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

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

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

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

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

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

(d) *Comparison of other features.* The SE Report must include descriptions of any other features of the new and

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

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

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

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

(A) The constituent names in alphabetical order;

(B) The common name(s);

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

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

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

(F) The analytical methods used and associated reference(s);

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

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

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

(J) Full test data (including test protocols, any deviation(s) from the test protocols, quantitative acceptance (pass/fail) criteria and complete data sets) for all testing performed.

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

(e) *Stability information.* For smokeless tobacco products and tobacco products that contain fermented tobacco, the SE Report must contain information on the stability of the new and predicate tobacco products, including the following information:

(1) A description of how the stability is indicated on the tobacco product, and an explanation as to whether the stability testing is identical for the predicate and the new tobacco product;

(2) Any known or expected impacts of the differences between the new and predicate products on the product stability. If no impact is known or expected, state that. For those products that contain fermented tobacco, the SE Report must provide information on the fermentation processing steps, including the composition of the inoculum, with species name(s) and concentration(s); pH; temperature; moisture content; water activity; duration; and added ingredients;

(3) Detailed stability testing, including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all stability testing performed. Stability testing must be performed at the beginning (zero time), middle, and end of the expected storage time for the chemical and microbial endpoints as follows: Microbial content data including total aerobic microbial count and total yeast and mold count along with identification of detected microbiological organisms by genus and species names (if applicable); pH; moisture content; water activity; tobacco-specific nitrosamines (total, N-nitrosonornicotine (NNN), 4-methylnitrosamino)-1-(3-pydridyl)-1-butanone) (NNK)); nitrate and nitrite levels; preservatives and microbial metabolic inhibitors (if any); and method of heat treatment or pasteurization used to reduce microbial loads;

(4) Testing information, including the storage conditions for samples retained for testing; identification of the test methods used; 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 support for the expiration date (*e.g.,* by showing that an adequate number of batches was tested);

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

(6) Identification of microbiological organisms by genus and species names, where applicable, and culture collection number either used during the manufacturing process and/or detected through stability testing.

(f) *Applicant's basis for substantial equivalence determination.* The applicant must state that the new tobacco product has either:

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

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (§ 1107.19(a)); heating source (§ 1107.19(b)); materials and ingredients (§ 1107.19(c)); and other features (§ 1107.19(d)). In addition, to demonstrate that a new tobacco product with different characteristics is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not raise different questions of public health (§ 1107.19(e)).

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

§ 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.

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

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

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

§ 1107.22 Withdrawal by applicant.

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

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

(2) The submission tracking number; and

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

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

(c) The SE Report is an agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The availability of the withdrawn SE Report will be subject to FDA's public information regulations in § 20.45 of this chapter.

§ 1107.24 Change in ownership of an SE Report.

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

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

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

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

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

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under § 1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with 21 CFR part 20. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in § 20.45 of this chapter; and

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

Subpart D—FDA Review

§ 1107.40 Communications between FDA and applicants.

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

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

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

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

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

§ 1107.42 Review cycles.

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

(b) *Additional review cycles.* If FDA issues a deficiency notification under § 1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the applicant fails to respond within the time period provided in the notification of deficiency, FDA will issue an order denying marketing authorization under the criteria set forth in § 1107.48. If the applicant's response to the notification of deficiencies provides the information FDA requested, but FDA identifies additional deficiencies, FDA may issue an additional deficiency notification. Each response will begin a new 90-day review cycle.

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

§ 1107.44 FDA action on an SE Report.

After receipt of an SE Report, FDA will:

(a) Refuse to accept the SE Report if it does not comply with § 1107.18;

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

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

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

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

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

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

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

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

If FDA finds that the information submitted in the SE Report establishes that the new tobacco product is substantially equivalent to a predicate tobacco product that was commercially marketed in the United States on February 15, 2007, and finds that the new tobacco product is in compliance with the requirements of the Federal

Food, Drug, and Cosmetic Act, FDA will send the applicant an order authorizing marketing of the product. A marketing authorization order becomes effective on the date the order is issued.

§ 1107.48 Issuance of an order denying marketing authorization.

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

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

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

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

§ 1107.50 Rescission of order.

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

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

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

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

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

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

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

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

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

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

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

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

Subpart E—Miscellaneous

§ 1107.58 Record retention.

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

§ 1107.60 Confidentiality.

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

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

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

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

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

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

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

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

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

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

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

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

(5) In accordance with § 25.51 of the chapter (21 CFR 25.51), the environmental assessment or, if applicable, the claim of categorical exclusion from the requirement to

submit an environmental assessment under part 25 of this chapter.

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

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

§ 1107.62 Electronic submission.

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

(b) *Waivers from electronic format requirement.* An applicant may submit a written request that is legible and written in English, to the Center for Tobacco Products asking that FDA waive the requirement for electronic format and content. Waivers will be granted if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants can send the written request to the address included on our website (*www.fda.gov/tobaccoproducts*). The request must include the following information:

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

(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.

Dated: March 21, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

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