Guidance for Industry

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)*

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with Docket No. FDA-2011-D-0147. For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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*This is a revision to the first edition of this guidance, which FDA issued March 4, 2015. A summary of the revisions is at the end of the guidance.

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Guidance for Industry[1]

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information in response to frequently asked questions (FAQs) that the Center for Tobacco Products (CTP) is receiving from manufacturers and other interested stakeholders (you) on demonstrating the substantial equivalence (SE) of a new tobacco product. In January 2011, FDA issued guidance regarding the submission of substantial equivalence reports (SE Reports) under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 387e(j)).[2] In September 2011, FDA issued draft guidance responding to frequently asked questions covering a range of topics on demonstrating the SE of a new tobacco product.[3] In March 2015, FDA issued a final guidance on many of the topics in the September 2011 Draft FAQ Guidance.[4] After carefully reviewing and considering comments submitted on the March 2015 FAQ

[1] This guidance was prepared by the Office of Science and Office of Regulations in the Center for Tobacco Products at FDA.

[2] Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (Demonstrating SE Guidance) available on the Internet at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf The notice of availability for this guidance published on January 6, 2011 (76 Federal Register 789).

[3] Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions, Draft Guidance for Industry and FDA Staff (September 2011 Draft FAQ Guidance). The notice of availability for the draft guidance published on September 9, 2011 (76 Federal Register 55927).

[4] Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (March 2015 FAQ Guidance). The notice of availability for the guidance published on March 5, 2015 (80 Federal Register 12011).

Guidance, FDA is issuing this revised final guidance to provide further information and clarification on the topics addressed in the March 2015 FAQ Guidance.

This guidance describes FDA's current thinking on whether and when a change to a tobacco product's label, product quantity in the package, additives, or specifications renders that later product a "new tobacco product" subject to premarket review (whether or not the new tobacco product replaces the original tobacco product). It explains that a manufacturer may submit streamlined SE Reports for certain modifications to labels and changes to product quantity as an alternative to the more comprehensive (full) SE Reports described in the Demonstrating SE Guidance. The guidance also explains FDA's plans and processes for review of the streamlined SE Reports. Finally, this guidance responds to several questions that have been raised about the SE process more generally.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Overview of Premarket Review

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, and provided FDA with broad authority to regulate tobacco products under the FD&C Act. The FD&C Act generally requires that a tobacco product manufacturer submit a premarket application and obtain a marketing authorization order before the manufacturer may introduce a new tobacco product into interstate commerce (section 910) (21 U.S.C. 387j)). A new tobacco product that does not comply with the premarket requirements of sections 905(j) and 910 of the FD&C Act is both misbranded and adulterated (sections 902(6)(A) and 903(a)(6) of the FD&C Act (21 U.S.C. 387b(6)(A) and 387c(a)(6))).

A premarket application and a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act are not required, however, if a manufacturer submits an SE Report to FDA under section 905(j) (21 U.S.C. 387e(j)) and obtains an order under section 910(a)(2) finding that the new tobacco product is (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, and (2) in compliance with the requirements of the FD&C Act.

If a new tobacco product has been modified by adding or deleting a tobacco additive or increasing or decreasing the quantity of an existing tobacco additive, the manufacturer may, instead of a premarket application under section 910(b), submit an exemption request under 21 CFR 1107.1. FDA may grant the exemption request if it determines that (1) the modification is a minor modification of a tobacco product that can be sold under

the FD&C Act, (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the product to be marketed would be appropriate for protection of the public health, and (3) an exemption is otherwise appropriate.

If FDA grants an exemption from the substantial equivalence requirements, manufacturers must also submit a report under section 905(j)(1)(A)(ii), at least 90 days prior to introduction or delivery of the product into interstate commerce, stating (1) the tobacco product is modified within the meaning of the exemptions provision, (2) the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, (3) all of the modifications are covered by exemptions granted under section 905(j)(3) of the FD&C Act, and (4) actions taken to ensure that the tobacco product is in compliance with section 907.

In sum, the FD&C Act requires all new tobacco products to have premarket authorization. Section 910(a)(2).

B. Definition of "New Tobacco Product"

A threshold question for determining whether premarket review is required is whether a product is a "new tobacco product." The term new tobacco product means:

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

(Section 910(a)(1) of the FD&C Act (21 U.S.C. 387j(a)(1)).)

The term tobacco product is defined as "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)" (section 201(rr)(1) of the FD&C Act (21 U.S.C. 321(rr)(1))). This term does not include an article that is a drug, a device, or a combination product as defined in the FD&C Act (see section 201(rr) of the FD&C Act).

In the March 2015 FAQ Guidance, FDA explained that, if a product's label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, it is a new product under section 910(a)(1)(A) of the FD&C Act because that product was not commercially marketed in the United States as of February 15, 2007. This interpretation was a change from the September 2011 Draft FAQ Guidance, in which FDA indicated that it would consider the "label" of the tobacco

product to be a "part" of that tobacco product, and, accordingly, any modification to a tobacco product's label after February 15, 2007, would make the product a new product subject to premarket review. After reviewing the comments and information submitted in response to the September 2011 Draft FAQ Guidance, FDA in the March 2015 FAQ Guidance indicated that it had reconsidered its interpretation and concluded that a label is not a "part" of the tobacco product.

C. Submission and Review of an SE Report

The FD&C Act authorizes FDA to issue an order finding substantial equivalence when FDA finds that the new tobacco product, when compared to a predicate tobacco product, 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 more extensive premarket requirements because the product does not raise different questions of public health (section 910(a)(3)(A) of the FD&C Act).

The FD&C Act requires that, as part of an SE Report, the manufacturer provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request (section 910(a)(4)). The FD&C Act otherwise authorizes the agency to determine the form and manner of the substantial equivalence report (section 905(j)(1)). In the Demonstrating SE Guidance, FDA provided recommendations on the data and information that should be included in a full SE Report so that FDA could determine whether the new tobacco product is (1) substantially equivalent, within the meaning of section 910(a)(3) of the Act, to an appropriate predicate product, and (2) in compliance with the requirements of the Act (section 910(a)(2)(A) of the Act). Many of these recommendations applied to *all* SE Reports, "whether for a new tobacco product with the *same characteristics* as a predicate product" or "for a new tobacco product with *different characteristics*." (Demonstrating SE Guidance page 12).

The March 2015 FAQ Guidance offered two streamlined alternative SE Reports, one for label changes and one for product quantity changes, referred to as the "Same Characteristics SE Report" and the "Product Quantity Change SE Report" respectively. This guidance provides further information and clarifies FDA's recommendations with respect to the data and information included in these streamlined reports. As discussed further below, FDA is recommending that manufacturers provide less information in these reports as compared to the recommendations for the full SE Reports. Thus, these reports should be easier for industry to prepare and for FDA to review than full SE Reports.[5] FDA is also adopting processes and procedures to better enable the agency to

[5] Appendices 1 and 2 to this guidance provide a fictional example of what the Same Characteristics SE Report might look like. In addition, information that manufacturers might use to show grandfathered status is discussed in the September 2014 guidance document entitled, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm416495.htm). Additional information on preparing environmental assessments is provided at 21 CFR part 25.

review these streamlined reports expeditiously, including placing them in separate queues from full SE Reports.

II. RESPONSES TO FREQUENTLY ASKED QUESTIONS

This section provides our responses to questions that you have frequently asked us on the substantial equivalence provisions. The answers provided in this guidance are specific to premarket requirements of the FD&C Act and are not intended to speak to any other requirements of the FD&C Act. Manufacturers are encouraged to review the FD&C Act, the regulations in effect, and any available guidances.

A. Label Changes

This section of the guidance describes FDA's current thinking on when a change to a tobacco product label renders that product a "new tobacco product" subject to premarket review, describes the streamlined submission that may be submitted when a new tobacco product has the "same characteristics" as the predicate, and explains FDA's plans for review of such submissions.

Question 1:
Does a change in a product label render a product a "new tobacco product" subject to the premarket review provisions of the FD&C Act?

Response:
Yes, if a product's label is modified in any way that renders the product distinct from the predicate. Where consumers perceive a product as "new" by virtue of a new name or a distinctly different label (and sometimes manufacturers market these products as "new" in their advertisements and promotional materials), the product is new under section 910(a)(1)(A) of the FD&C Act because that product "was not commercially marketed in the United States as of February 15, 2007." For example, if Company A had been marketing Brand X and recently started to market both Brand X and Brand Y, Brand Y is a new tobacco product even if it has the same characteristics as Brand X because Brand Y "was not commercially marketed in the United States as of February 15, 2007."

As explained above, manufacturers may utilize the substantial equivalence pathway to obtain premarket authorization for their new tobacco products. Moreover, Congress established that the SE pathway is available to manufacturers seeking premarket authorization for a new product that has the same physical characteristics as the predicate product. In the Tobacco Control Act, Congress described two sets of criteria for FDA to apply in finding a product substantially equivalent:

(i) a product has "the *same characteristics* as the predicate tobacco product;" or
(ii) a product has "*different characteristics* and the information submitted contains information … that demonstrates that … it is not appropriate

> to regulate the product under [the PMTA provisions] because *the product does not raise different questions of public health*."

FD&C Act § 910(a)(3)(A) (emphasis added). [6] Thus, Congress clearly contemplated that SE Reports would be submitted for products that had the same characteristics as the predicate.

The FD&C Act defines "characteristics" broadly as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product" (Section 910(a)(3)(B)). Because these "characteristics" appear to focus on physical attributes of the product, FDA interprets the "different characteristics" prong of the SE criteria to refer to changes in the physical attributes of the product. Thus, the "same characteristics" prong of the SE criteria describes products whose physical attributes are identical to those of the predicate. Accordingly, Congress must have contemplated that there would be "new tobacco products" that were physically identical to predicate products that would be cleared for marketing under the "same characteristics" prong. Products that carry new names or label modifications that render the product distinct, but otherwise have the same physical attributes as a predicate product, fall into this category.

This interpretation is consistent with FDA's interpretation of other provisions of the Tobacco Control Act in terms of the changes that create a distinct product with attendant regulatory consequences. The FD&C Act defines "brand" as "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" (Section 900(2)). The product listing and the ingredient and harmful and potentially harmful constituents (HPHC) reporting requirements distinguish among products by their "brands." A tobacco product establishment owner/operator is required to list all of its tobacco products that the person has introduced for commercial distribution (section 905(i)(1)). The list is submitted as part of annual registration and updated biannually with any changes (section 905(i)(3)). FDA issued guidance which explains that the obligation to update the list can be prompted by a change in the "brand/sub-brand or other commercial name."[7] A tobacco manufacturer must also report ingredients and HPHCs to FDA by "brand and subbrand"

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[6] For devices, the substantial equivalence provision specifically defines "different technological characteristics" as meaning "there is a significant change in the materials, design, energy source, or other features of the device." § 513(i)(1)(B). This is in contrast to tobacco products, which does not define "same characteristics" or "different characteristics." Moreover, under the section 905(j)(3), FDA can exempt certain minor modifications in products from pre-market review. Where a manufacturer makes certain minor changes to its product, and as such the product no longer has identical characteristics, a product that would otherwise require premarket review is exempted from such a process. Hence, Congress provided a premarket pathway for minor changes to a product that results in different characteristics, outside of the "same characteristics" SE pathway.

[7] FDA's Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (April 2014) ("[e]ach product [in a listing] is to be clearly and uniquely identified by the product category (e.g., cigarette, smokeless tobacco, paper, filter) and unique name (i.e., brand/sub-brand or other commercial name used in commercial distribution)" (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm189539.htm).

(Sections 904(a)(1) and (a)(3)). The statute further directs FDA to publicly post the HPHC information by "brand and subbrand" (Section 904(e)). Additionally, FDA allows companies to submit a single ingredient list for multiple products that have the same ingredients.[8]

Thus, changes in the brand name, label, and identifiable pattern of colors may create a distinct product that would require a separate entry for listing and ingredient/HPHC reporting purposes.

Parallels and similarities in the listing, reporting, and substantial equivalence provisions further support the view that Congress intended that each product a company adds to its listing be subject to a premarket authorization prior to commercial distribution. A tobacco product must be added to a company's product listing if it is "for commercial distribution" and is not yet listed (Section 905(i)). The manufacturer must report ingredients and HPHCs for a product "not on the market" and must do so at least 90 days prior to the delivery for introduction into interstate commerce of that product (Section 904(c)(1)). Each person who is required to register and "proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use" that is not grandfathered shall submit an SE Report at least "90 days prior to making such introduction or delivery…" (Section 905(j)). The similarity in these provisions suggests that Congress contemplated that tobacco manufacturers who intended to introduce a tobacco product that was distinct from an earlier marketed product but had identical physical attributes would list the product, report on its ingredients and HPHCs, and submit an SE Report explaining that the product had the same characteristics as a predicate product. For example, if a company markets "Private Label Version," and subsequently markets "Brand Name Version," both products are distinct products even if "Brand Name Version" has the same characteristics as "Private Label Version." The company would be required to list the "Brand Name Version" product, report on its ingredients and HPHCs, and submit an appropriate SE Report.

Question 2:
What types of changes make a product's label distinct from the predicate?

Response:
FDA recommends that companies examine the definition of "brand" as analogous authority: "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" (Section 900(2)). Some types of changes to the label that might result in a distinct product are changes to logo, identifiable patterns of color, product descriptors, or any combination thereof. In determining whether such change is sufficient to result in distinct product,

[8] FDA's Guidance for Industry: Listing of Ingredients in Tobacco Products (November 2009) (http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf).

FDA intends to consider whether the label change would lead consumers to believe that the product is different from another tobacco product. That is, when a company changes the label of a tobacco product, FDA believes it is a new product if consumers are likely to perceive it as "new" by virtue of the different label.

In contrast, a change to a logo, colors, product descriptors, or other aspects of the label that is unlikely to lead consumers to believe that the product is different from the predicate would not result in a new tobacco product. In such cases, there would be no reporting requirement triggered under section 910. This chart provides some basic examples.

Label Change	**Examples that May Result in a Distinct Product**	**Examples that May Not Result in a Distinct Product**
Background Color	Green to Red	White to Cream
Logo Image	Changing the object depicted in the logo (e.g., star to lion)	The same object on the logo, but reduced size on label
Product Descriptors	Addition of "Premium Tobacco"	Italicizing product descriptors that are on the label

Question 3:
Would a tobacco product be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the tobacco product was commercially marketed as of February 15, 2007 and the manufacturer changed the name of the product? In other words, if a manufacturer changes the name of its product, does this modify the product in a way that makes it distinct?

Response:
Yes. If a tobacco product was commercially marketed as of February 15, 2007, but subsequently the manufacturer changes the tobacco product's name, this makes the product distinct. Therefore, the distinct product is a new tobacco product under section 910(a)(1)(A) of the FD&C Act. If, however, the product's characteristics are the same as the predicate, the manufacturer may submit a Same Characteristics SE Report for this change as discussed in the response to question 6. For example, if the logo on a tobacco product's label is modified in a way that makes the tobacco product distinct, but the characteristics of the product remain the same, the manufacturer may submit the Same Characteristics SE Report.

Question 4:
What purpose is served by the submission of the Same Characteristics SE Report?

Response:
Pursuant to section 910 of the Tobacco Control Act, all new tobacco products are subject to premarket review. As discussed in the response to question 1, the Same Characteristics SE Report is intended to provide FDA with information needed to conduct the premarket review and issue the order required before a new tobacco product may be marketed (section 910). Underlying these premarket requirements are concerns Congress identified when it enacted the Tobacco Control Act and provided FDA with broad authority to regulate the introduction, marketing and advertising of tobacco products. Congress found that such regulation would provide significant health and economic benefits to the public. See Tobacco Control Act, Section 2, Finding 12. Requiring SE Reports helps FDA keep abreast of products in marketplace so that it can properly evaluate whether products are in compliance with the Act, for example whether they are legally marketed. One way FDA may determine marketing status is to use the product listing database as a starting point to determine compliance status. Thus, when FDA finds a product on the market, it can check the database to determine whether the product is listed. When a product is listed, FDA can cross-check its marketing authorizations to determine whether the product is lawfully on the market. In considering this in the context of products that are distinct but have identical physical attributes, an SE submission and an SE order enable FDA to determine whether the product is lawfully on the market.

Question 5:
When I have a tobacco product that is distinct from, but has the same characteristics as, a product of mine that was commercially marketed as of February 15, 2007 (or a product of mine that has been found by FDA to be SE), should I submit a full SE Report that contains all of the information FDA recommends including in its Demonstrating SE Guidance?

Response:
No. Section 905(j) authorizes the agency to determine the form and manner of the substantial equivalence report. If you have a tobacco product that is distinct, e.g., it has a different name, but has the same characteristics as either a tobacco product that you manufactured that was commercially marketed as of February 15, 2007, or a product that has been found by FDA to be substantially equivalent, you may submit a SE Report that contains a brief, specific set of information (Same Characteristics SE Report).

The material in a Same Characteristics SE Report is substantially more limited and less burdensome than for full SE Reports. FDA believes the information included in the Same Characteristics SE Report should be sufficient for FDA to make its SE determination in this situation. This Same Characteristics SE Report should be easier for industry to prepare and for FDA to review than would typically be the case for SE reports involving other changes to a tobacco product. More information related to the Same Characteristics SE Report is provided in the following questions and responses.

Question 6:
What information should a Same Characteristics SE Report contain?

Response:
The following items should be included in your Same Characteristics SE Report:

- A cover letter that prominently identifies the submission as **"Same Characteristics SE Report."**
- Full identification of your new tobacco product:[9]
  - manufacturer (FDA expects the manufacturer of the new product will generally be the same as the manufacturer of the predicate product. If this is not the case, FDA would need adequate assurances that the new product has the same characteristics as the predicate product, and believes the certification below would not suffice. In such a case, we strongly encourage the applicant to contact CTP to request a meeting[10] about possible ways to provide adequate assurances that the characteristics remain the same.),
  - unique name (i.e., brand name/subbrand or other commercial name used in commercial distribution),
  - product category (e.g., cigarette),
  - product subcategory (e.g., conventional filtered), and
  - package size/count (e.g., 7.8 oz. or 20 cigarettes per pack)
  - if portioned, portion size (e.g., 0.5 gram bag of snus)
  - package type (e.g., soft pack, box, plastic can with metal lid, bag)
  - any other information needed to uniquely identify the new tobacco product.[11] (FDA has received Same Characteristics SE Reports where the applicant has included some information relating to unique identification, such as brand name, but the provided information does not in fact uniquely identify the product. Common instances where such discrepancies have occurred include SE Reports where the provided identifying information, such as brand name, product subcategory, etc., has actually covered multiple tobacco products, for example cigarettes with varying diameters, lengths, ventilation and/or characterizing flavors. In these instances, FDA has been unable to determine the identification of the predicate and/or new product. Therefore, an applicant should provide CTP with anything else needed to uniquely identify the product, including, for example, diameter, length, ventilation, and characterizing flavor as necessary.)

[9] The new tobacco product is the tobacco product that is distinct because, e.g., of its different name, logo, packaging font or color, but is otherwise identical (i.e., has exactly the same characteristics as a predicate tobacco product).
[10] For additional information on meetings, please refer to the CTP guidance, "*Meetings with Industry and Investigators on the Research and Development of Tobacco Products*" (CTP Meetings Guidance) available on the Internet at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM305282.pdf. This guidance provides information on how to request a meeting, along with recommendations about what to include in a request, etc.
[11] If you have questions on information relating to unique identification for your product we encourage you to contact your assigned regulatory health project manager or to review recent order letters posted.

- Full identification of a predicate tobacco product:[12]
  - manufacturer
  - unique name (i.e., brand name/subbrand or other commercial name used in commercial distribution),
  - product category (e.g., cigarette),
  - product subcategory (e.g., conventional filtered), and
  - package size/count (e.g., 7.8 oz. or 20 cigarettes per pack)
  - if portioned, portion size (e.g., 0.5 gram bag of snus)
  - package type (e.g., soft pack, box, plastic can with metal lid, bag)
  - any other information needed to uniquely identify the predicate tobacco product [13]. (FDA has received Same Characteristics SE Reports where the applicant has included some information relating to unique identification, such as brand name, but the provided information does not in fact uniquely identify the product. Common instances where such discrepancies have occurred include SE Reports where the provided identifying information, such as brand name, product subcategory, etc., has actually covered multiple tobacco products, for example cigarettes with varying diameters, lengths, ventilation and/or characterizing flavors. In these instances, FDA has been unable to determine the identification of the predicate and/or new product. Therefore, an applicant should provide CTP with anything else needed to uniquely identify the product, including, for example, diameter, length, ventilation, and characterizing flavor as necessary.)
- If you have previously submitted an SE Report for the new tobacco product, you should include the Submission Tracking Number (STN) assigned by FDA to that previous SE Report. (You should also review the responses to questions 4 and 5.)
- Statement of whether you intend to commercially distribute both the predicate tobacco product and the new tobacco product, or only the new tobacco product (please also see the response to question 12).
- Environmental Assessment (please also see the response to question 36).
- Health Information Summary or a statement that the "information will be made available upon request by any person" (section 910(a)(4) of the FD&C Act).
- Statement of action taken to comply with the requirements under section 907 of the FD&C Act that are applicable to the tobacco product (or a statement that "requirements under section 907 are not applicable to the tobacco product").

[12] The predicate tobacco product for a Same Characteristics SE Report is a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007, or a tobacco product that has been found substantially equivalent, and that has identical characteristics to the new tobacco product.

[13] If you have questions on information relating to unique identification for your product we encourage you to contact your assigned regulatory health project manager or to review recent order letters posted.

- Certification statement that is signed by a responsible official who is authorized to act on behalf of the company and that states the following: [14]

  I, [insert name of responsible official], on behalf of [insert name of company], certify that [insert new tobacco product name] has a different [identify distinction] from [insert name of predicate tobacco product] but is otherwise identical to [insert name of predicate tobacco product]. I certify that [insert name of company] understands this means there is no modification, except for [identify distinction] from the predicate tobacco product, including any change in materials, ingredients, design features, heating source, or any other features. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Question 7:
How will FDA review Same Characteristics SE Reports?

Response:
There are far fewer materials and information to be submitted in a Same Characteristics SE Report than a typical SE report, and the findings are fairly straight-forward. FDA anticipates that, so long as the appropriate information is included, its review time should be much less than SE review generally. FDA intends to review Same Characteristics SE Reports in a separate queue.

Due to the far fewer materials and information, FDA intends to conduct a maximum of two review cycles[15] for issuance of a decision to a Same Characteristics SE Report.

In April 2014 FDA established performance measures that include timeframes for review of regular SE reports. Those performance measures were created for the "full" SE Report that included a detailed comparison for each characteristic between the new and predicate product. As the Same Characteristics SE Reports contain far fewer materials for review, the performance measures have been expanded to reflect timeframes for review specific to Same Characteristics SE Reports. They can be found at: http://www.fda.gov/tobaccoproducts/newsevents/ucm393894.htm.

[14] The certification statement includes a reference to "materials, ingredients, design, composition, heating source, or other features," which section 910(B)(3) of the FD&C Act defines as characteristics. FDA also discussed these terms in the 2011 Demonstrating SE Guidance, pages 9-11.

[15] A review cycle ends with an action letter, e.g., a preliminary finding letter, scientific advice/information letter, SE order, or not substantially equivalent order. Thus, for example, the issuance of a preliminary finding letter would end the first cycle of review, and the issuance of an SE order would end the second cycle of review.

Question 8:
Do I need to submit the product label as part of my Same Characteristics SE Report?

Response:
No. A manufacturer does not need to submit any product label as part of its Same Characteristics SE Report, and FDA does not require the preapproval of the product's label before issuing an SE order.

Question 9:
If I currently have an SE Report pending with FDA, may I use the Same Characteristics SE Report instead?

Response:
If your pending report is for a new tobacco product that is distinct because, e.g., it has a different name, but it has the same characteristics as the predicate tobacco product, you may submit a Same Characteristics SE Report for the new product, or if this is to a provisional SE Report, you may you may amend your pending report with information to support a same characteristics SE report.

Question 10:
What if I wish to modify my tobacco product's label in a way that creates a distinct tobacco product and my original product is the subject of a "provisional"[16] SE Report that is pending review at FDA?

Response:
A provisionally marketed tobacco product can never serve as a valid predicate tobacco product. Under section 905(j)(1)(A)(i) of the FD&C Act, SE reports may compare new products only to products that were commercially marketed as of February 15, 2007, or products that FDA has previously determined to be substantially equivalent to a predicate tobacco product. Products that are the subject of "provisional" SE Reports, though legally sold or distributed, may not serve as predicate tobacco products under the FD&C Act unless they have been previously found to be SE.

However, FDA intends to exercise enforcement discretion and not take enforcement action against a new tobacco product that is marketed without a required marketing authorization order in the following situation:[17]

- The new tobacco product is distinct from, but has the same characteristics as, a product that is subject to a "provisional" SE Report for which FDA has not yet issued an order under section 910(a) of the FD&C Act;

[16] A "provisional" SE Report is one that was submitted prior to March 23, 2011, for a new tobacco product that was first commercially marketed between February 15, 2007, and March 22, 2011. New tobacco products that are the subjects of provisional SE Reports may remain on the market unless FDA finds the products not substantially equivalent (NSE) to a predicate product.
[17] Products may be subject to enforcement at any time for other violations of the FD&C Act.

- The manufacturer submits a Same Characteristics SE Report as outlined in the response to question 6 above. The Same Characteristics SE Report should identify the STN assigned by FDA for the original provisional SE Report, and provide information on the provisional product in lieu of the predicate information described in question 6; and
- The manufacturer does not commercially distribute the new tobacco product that is the subject of the Same Characteristics SE Report until 90 days (see Section 905(j)(1)) after FDA's receipt of the complete Same Characteristics SE Report (as outlined in the response to question 6 above); or for products already on the market as of the date of issuance of this guidance, if the manufacturer submits the complete Same Characteristics SE Report to be received by CTP **within 30 calendar days** of the date of the issuance of the second edition of this guidance (refer to the cover page of this guidance document for date of issuance). Because this explanation was also contained in the March 2015 FAQ Guidance, FDA is in essence extending this initial 30 day period to be 30 calendar days after the issuance of the second edition of this guidance.

FDA intends to issue an order on the new tobacco product that is the subject of the Same Characteristics SE Report only after it has completed its review of the "provisional" SE Report because, as explained above, products that are the subject of "provisional" SE reports may not serve as predicate tobacco products under the FD&C Act unless they have been previously found SE. Ultimately, if the product that is the subject of the "provisional" SE Report receives an SE order, FDA intends to then issue, if appropriate, an order for the new tobacco product that is the subject of the Same Characteristics SE Report. If the product that is the subject of the "provisional" SE Report receives a not substantially equivalent (NSE) order, FDA intends to take appropriate enforcement action if the new tobacco product that is the subject of the Same Characteristics SE Report continues to be marketed. In sum, if the product that is the subject of the "provisional" SE Report is found NSE, then neither it nor the distinct new product that is the subject of the Same Characteristics SE Report, may be introduced or delivered for introduction into interstate commerce for commercial distribution without first obtaining a marketing order (via a different pathway or a new SE Report); doing so would render the product adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act).

Question 11:
What if I have a tobacco product that is legally sold because it was commercially marketed as of February 15, 2007, but I have changed the product label in a way that makes it distinct and I am now selling that distinct product?

Response:
The tobacco product with the modified label that renders the product distinct is a new tobacco product subject to premarket requirements under section 910(a) of the FD&C Act. New tobacco products may not be sold or distributed in interstate commerce without an order from FDA under either section 910(c)(1)(A)(i) or section 910(a)(2)(A) of the FD&C Act. As outlined in the responses to questions 2 and 3, you may submit a Same

Characteristics SE Report for a label change that renders the product distinct, and FDA will determine whether the new tobacco product is substantially equivalent.

However, FDA does not intend to object to the commercial distribution of a new product that is distinct from, but has the same characteristics as, a product that is currently being sold or distributed in interstate commerce prior to FDA's issuance of an order under section 910(a) of the FD&C Act in the following situation:

- The manufacturer submits a Same Characteristics SE Report as outlined in the response to question 6 above, to be received by CTP **within 30 calendar days** of the date of issuance of the second edition of this guidance (refer to the cover page of this guidance document for the date of issuance). Because this explanation was also contained in the March 2015 FAQ Guidance, FDA is in essence extending this initial 30 day period by several months to be 30 calendar days after the issuance of the second edition of this guidance.

If, after review of the Same Characteristics SE Report, FDA finds that the new product that is the subject of the Same Characteristics SE Report is not SE (i.e., NSE) to the predicate tobacco product, then the compliance policy described above will no longer apply. In that case, the product could no longer be legally marketed and would be adulterated or misbranded under sections 902(6) and 903(a)(6) of the FD&C Act.

Question 12:
If a manufacturer commercially markets a tobacco product as "Brand X" as of February 15, 2007, and, after that date, continues to commercially market "Brand X" but also intends to commercially market an otherwise identical (i.e., same characteristics) tobacco product under the additional name "Brand Y," would "Brand Y" be a "new tobacco product" and subject to the substantial equivalence provisions?

Response:
Yes. "Brand Y" would be a new tobacco product under section 910(a)(1)(A) of the FD&C Act. If Brand Y is otherwise identical (i.e., same characteristics) to Brand X, the manufacturer may submit a Same Characteristics SE Report for the new product as discussed in the response to question 6. The Same Characteristics SE Report should indicate whether the manufacturer intends to commercially market both the Brand X product and the Brand Y product.

Question 13:
If a manufacturer commercially markets a cigarette product as "Brand A" as of February 15, 2007, but also intends to commercially market an otherwise identical (i.e., same characteristics) tobacco product as "Brand AtoZ", except that "Brand AtoZ" has a different brand name ink-stamped on each stick or omits the brand name ink-stamp that appears on each stick of the predicate product, may the Same Characteristics SE Report be used?

Response:
No. The product "Brand AtoZ" is not identical (i.e., same characteristics) to the product "Brand A" if there is a difference in ink-stamping on each cigarette. To have the same characteristics as a predicate product means that the characteristics (i.e., the materials, ingredients, design, composition, heating source, or other features) are identical. A difference in ink-stamping (e.g., a change in the name stamped, the addition of an ink stamp, or deletion of an ink stamp) is a change in ingredients. Thus these changes in ink stamping would mean the new product has different characteristics than the predicate product.

B. Product Quantity Changes

This section of the guidance describes FDA's current thinking on whether and when a change to a product quantity in the package renders that product a "new tobacco product" subject to premarket review, describes the streamlined submission that may be submitted when a new tobacco product has changes to product quantity but all other product characteristics remain the same, and explains FDA's plans for review of such submissions.

Question 14:
Does a change to a product quantity in the package render a product a "new tobacco product" subject to the premarket review provisions of the FD&C Act?

Response:
Yes, the introduction of a product for which the product quantity in the package[18] has changed (e.g., the number of portioned parts per package has changed such that the new product would hold 24 cigarettes per pack instead of 20; the weight of the product has changed such that the new smokeless package would change from 24 grams to 5 grams), even if the per weight composition[19] of additives, ingredients, and other features remains the same, renders it a new product under section 910(a)(1) of the FD&C Act because the characteristics (e.g., amounts of ingredients, materials, other features, etc.) have changed. As defined in section 910(a)(1), a new tobacco product is:

> (A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or,
> (B) 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.

[18] For example, the pack, box, carton, container, or wrapping (such as cellophane), in which a tobacco product is sold to consumers.
[19] The manner in which the materials (e.g., ingredients, additives, and biological organisms) are arranged and integrated to produce a finished tobacco product.

Changing a product by altering the quantity in the package is a modification of that product (e.g., a change in amounts of ingredients, materials, other features) resulting in a new product under section 910(a)(1), thus requiring premarket authorization. However, we have determined that changes to product quantity (when all other product characteristics remain the same) will require a reduced set of information in order for FDA to determine whether the new product is substantially equivalent within the meaning of section 910(a)(3). Thus, if a product quantity has changed, but the per weight composition, design features, heating source, and all other features are otherwise identical to the predicate tobacco product, the manufacturer or importer may opt to submit a "Product Quantity Change SE Report"[20] as discussed in more detail in the following questions and answers.

Question 15:
Would a tobacco product be a "new tobacco product," and subject to the substantial equivalence provisions of the FD&C Act, if the tobacco product was commercially marketed as of February 15, 2007, but subsequently the quantity of product sold in a package is changed (e.g., the number of portioned parts per package has changed such that the new product would hold 24 cigarettes per pack instead of 20; the weight of the product has changed such that the new smokeless package would change from 24 grams to 5 grams)?

Response:
Yes. If a tobacco product was commercially marketed as of February 15, 2007, but subsequently the quantity of the tobacco product is changed, the product is a new tobacco product under section 910(a)(1) of the FD&C Act. If the only change to the tobacco product is a change to product quantity and the per weight composition inside the package remains identical, the manufacturer may submit a Product Quantity Change SE Report as an alternative to a full (more detailed) SE report or premarket application under section 910(b) of the FD&C Act (as discussed in the response to question 18).

Question 16:
What purpose is served by the submission of the Product Quantity Change SE Reports?

Response:
As discussed in the response to question 14, the Product Quantity Change SE Report provides FDA with information needed to conduct the premarket review and issue the order required before a new tobacco product may be marketed (section 910). Congress enacted the Tobacco Control Act to provide FDA with broad authority to regulate the introduction, marketing and advertising of tobacco products based in large part on its determination that such regulation would provide significant health and economic benefits to the public. See Tobacco Control Act, Finding 12. Congress also directed FDA to reissue a 1996 final rule that imposed restrictions on breaking apart cigarette and smokeless packages because of concerns about quantity and use by youth (section 102 of

[20] As described in this section, the Product Quantity Change SE Report would be an alternative to submitting a full SE report or a premarket application under section 910(b) of the FD&C Act.

the Tobacco Control Act; 21 CFR 1140.14(d)). Product Quantity Change SE Reports involve modifications that result in the new tobacco product having different characteristics from the predicate tobacco product. A change in quantity is a change to the amount of ingredients, materials, and other features within the new tobacco product as compared to the predicate tobacco product. The Product Quantity Change SE report is intended to provide manufacturers with a more limited and less burdensome report to support a determination that the new product does not raise different questions of public health.

Changes in product quantity can affect initiation and cessation, such as by affecting consumer harm perceptions, use intentions, and use behavior. The information in these Product Quantity Change SE Reports would allow for FDA to fully evaluate the potential of such changes in product quantity to determine whether the new product raises different questions of public health such that the product should be required to submit a premarket application. Smaller product quantities may allow for increased product uptake due to lower barriers to trying the product, are associated with lower product harm perceptions, and reduce product costs or increase product availability, all of which may affect use intentions and behavior, including initiation among youth.[21] Larger product quantities can potentially reduce cessation behaviors and increase tobacco product use among current users.[22] Additionally, changes in product quantity may make the product appear novel to consumers, increasing appeal and lowering harm perceptions, both of which may lead to increased product use and initiation. Failure to submit such data, or submission of assertions without scientific justification, hinders FDA's ability to fully evaluate the effects of product quantity changes and determine whether the new product raises different questions of public health.

Additionally, similar to the Same Characteristics SE Reports, another important purpose of requiring these SE Reports is to help FDA keep abreast of products in the marketplace so that it can properly evaluate whether products are in compliance with the Act. Please see the response under Question 4 for discussion on this topic.

Question 17:
When I have a tobacco product that is to be marketed in a different quantity, but is otherwise identical to one of my products that was commercially marketed as of February 15, 2007 (or one of my products that has been found by FDA to be SE), should I submit a full SE Report that contains all of the information FDA recommends including in its Demonstrating SE Guidance?

[21] Rogers, E.M. (2003). Diffusion of innovations (5th ed.). New York: Free Press; Ford, A., Moodie, C., & Hastings, G. (2012). The role of packaging for consumer products: Understanding the move towards 'plain' tobacco packaging. Addiction Research and Theory, 20, 339-347. doi:10.3109/16066359.2011.632700; Chaloupka, F. J., & Warner, K. E. (2000). The economics of smoking. NBER Working Paper no. 7047. Cambridge, MA.: National Bureau of Economic Research.
[22] Wertenbroch, K. (1998). Consumption self-control by rationing purchase quantities of virtue and vice. Marketing Science, 17, 317-337.

Response:
No. Section 905(j) authorizes the agency to determine the form and manner of the substantial equivalence report. FDA has determined that, if you have a tobacco product that is provided in a different quantity, but is otherwise identical (i.e., the per weight composition, design features, heating source, and other features of the product all remain the same) to either a tobacco product that was commercially marketed as of February 15, 2007, or a product that has been found by FDA to be substantially equivalent, you may submit a streamlined SE Report that contains a brief, specific set of information (Product Quantity Change SE Report). This may occur where the number of portioned parts per package has changed such that the new product would hold, e.g., 24 cigarettes per pack instead of 20, or the weight of smokeless package would change, e.g., from 24 grams to 5 grams.

The material that should be submitted in a Product Quantity SE Report is substantially more limited and less burdensome than for full SE Reports. We believe the information included in the Product Quantity Change SE Report should be sufficient for FDA to make its SE determination in this situation. This Product Quantity Change SE Report should be easier for industry to prepare and for FDA to review than would typically be the case for SE reports involving other changes to a tobacco product and, therefore, FDA expects to review these reports more quickly. More information related to the Product Quantity Change SE Report is provided in the following questions and responses.

Question 18:
What information should a Product Quantity Change SE Report contain?

Response:
The following items should be included in your Product Quantity Change SE Report:

- A cover letter that prominently identifies the submission as **"Product Quantity Change SE Report."**
- Full identification of your new tobacco product:[23]
  - — manufacturer (We expect the manufacturer of the new product will generally be the same as the manufacturer of the predicate product. If this is not the case, FDA would need adequate assurances that the new product has the same characteristics as the predicate product, and believes the certification below would not suffice. In such a case, we strongly encourage the applicant to contact FDA about possible ways to provide adequate assurances that the characteristics remain the same.),
  - — unique name (i.e., brand name/subbrand or other commercial name used in commercial distribution),
  - — product category (e.g., cigarette),
  - — product subcategory (e.g., conventional filtered), and
  - — package size/count (e.g., 7.8 oz. or 20 cigarettes per pack)
  - — if portioned, portion size (e.g., 0.5 gram bag of snus)

[23] The new tobacco product is the tobacco product that has a different product quantity, but the per weight composition inside the package is unchanged.

  - package type (e.g., soft pack, box, plastic can with metal lid, bag)
  - any other information needed to uniquely identify the new tobacco product[24]. (FDA has received Same Characteristics SE Reports where the applicant has included some information relating to unique identification, such as brand name, but the provided information does not in fact uniquely identify the product. Common instances where such discrepancies have occurred include SE Reports where the provided identifying information, such as brand name, product subcategory, etc., has actually covered multiple tobacco products, for example cigarettes with varying diameters, lengths, ventilation and/or characterizing flavors. In these instances, FDA has been unable to determine the identification of the predicate and/or new product. Therefore, an applicant should provide CTP with anything else needed to uniquely identify the product, including, for example, diameter, length, ventilation, and characterizing flavor as necessary.)
- Full identification of a predicate tobacco product:[25]
  - manufacturer,
  - unique name (i.e., brand name/subbrand or other commercial name used in commercial distribution),
  - product category (e.g., cigarette),
  - product subcategory (e.g., conventional filtered), and
  - package size/count (e.g., 7.8 oz. or 20 cigarettes per pack)
  - if portioned, portion size (e.g., 0.5 gram bag of snus)
  - package type (e.g., soft pack, box, plastic can with metal lid, bag)
  - any other information needed to uniquely identify the predicate tobacco product[26]. (FDA has received Same Characteristics SE Reports where the applicant has included some information relating to unique identification, such as brand name, but the provided information does not in fact uniquely identify the product. Common instances where such discrepancies have occurred include SE Reports where the provided identifying information, such as brand name, product subcategory, etc., has actually covered multiple tobacco products, for example cigarettes with varying diameters, lengths, ventilation and/or characterizing flavors. In these instances, FDA has been unable to determine the identification of the predicate and/or new product. Therefore, an applicant should provide CTP with anything else needed to uniquely identify the product, including, for example, diameter, length, ventilation, and characterizing flavor as necessary.)

[24] If you have questions on information relating to unique identification for your product we encourage you to contact your assigned regulatory health project manager or to review recent order letters posted.
[25] The predicate tobacco product for a Product Quantity Change SE Report is a tobacco product commercially marketed (other than for test marketing) as of February 15, 2007, or a tobacco product that has been found substantially equivalent and that is otherwise identical (i.e., the per weight composition of the product inside the package is unchanged) to the new tobacco product, except that the new tobacco product is packaged in a different product quantity.
[26] If you have questions on information relating to unique identification for your product we encourage you to contact your assigned regulatory health project manager or to review recent order letters posted.

- Scientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product compared to the predicate product
    - Some examples of scientific data include but are not limited to:
        - Studies on purchasing frequency that demonstrate that the amount of product used per day or per week is similar between the predicate and new tobacco products. For example, if you double the count of a portioned tobacco product (e.g., cigarette, pouched snus) or the total amount of an unportioned tobacco product in a single package (e.g., loose moist snuff) offered for purchase, the amount of product per use and per week that users consume is similar.
        - Studies showing that young adults are not more likely to purchase packages that are of lower total quantity compared to older adults.
        - Studies showing that products of lower quantity are not more likely to be purchased as impulse purchases.
        - Peer-reviewed publications supporting that this specific change in product quantity does not substantially alter consumer behavior.
        - Biomarkers of exposure that reflect product use and demonstrate that exposure is similar between use of the predicate and new tobacco products.
- Statement of whether you intend to commercially distribute both the predicate and new tobacco products, or only the new tobacco product, if it is found SE.
- Environmental Assessment (please also see the response to question 36).
- Health Information Summary or a statement that the "information will be made available upon request by any person" (section 910(a)(4) of the FD&C Act).
- Statement of action taken to comply with the requirements under section 907 of the FD&C Act that are applicable to the tobacco product (or a statement that "requirements under section 907 of the FD&C Act are not applicable to the tobacco product").
- Certification statement that is signed by a responsible official who is authorized to act on behalf of the company and that states the following:

  I, [insert name of responsible official], on behalf of [insert name of company], certify that [insert new tobacco product name] is packaged in a different quantity from [insert name of predicate tobacco product] but is otherwise identical to [insert name of predicate tobacco product]. I certify that [insert name of company] understands this means there is <u>no</u> modification, except in product quantity from the predicate tobacco product, including any change in per weight composition, design features, heating source, or other features. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who makes a materially

false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Question 19:
How will FDA review Product Quantity Change SE Reports?

Response:
There are far fewer materials and information to be submitted in a Product Quantity Change SE Report than a typical SE report, and the findings are fairly straight-forward. FDA anticipates that, so long as the appropriate information is included, its review time should be much less than SE review generally. FDA intends to review Product Quantity Change SE Reports in a queue separate from SE Reports involving other changes to a tobacco product.

Due to the far fewer materials, FDA is prepared to commit to a maximum of two review cycles[27] for issuance of a decision to a Product Quantity Change SE Report.

In April 2014 FDA established performance measures that include timeframes for review of regular SE reports. Those performance measures were created for the "full" SE Report that included a detailed comparison for each characteristic between the new and predicate product. As the Product Quantity Change SE Reports contain far fewer materials for review, the performance measures have been expanded to reflect timeframes for review specific to Product Quantity Change SE Reports. They can be found at: http://www.fda.gov/tobaccoproducts/newsevents/ucm393894.htm.

Question 20:
If I currently have an SE Report pending with FDA, may I use the Product Quantity Change SE Report instead?

Response:
If your pending report is for a new tobacco product that has only a different product quantity, but is otherwise identical to a predicate tobacco product, you may submit a Product Quantity Change SE Report for the new product, or if this is to a provisional SE Report, you may amend your pending report with all the information to support the product quantity change.

Question 21:
Can I change the quantity of product sold in a package if the product is the subject of a "provisional"[28] SE Report that is pending review at FDA?

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[27] A review cycle ends with an action letter, e.g., a preliminary finding letter, scientific advice/information letter, SE order, or not substantially equivalent order. Thus, for example, the issuance of a preliminary finding letter would end the first cycle of review, and the issuance of an SE order would end the second cycle of review.

[28] A "provisional" SE Report is one that was submitted prior to March 23, 2011, for a new tobacco product that was first commercially marketed between February 15, 2007, and March 22, 2011. New tobacco

Response:
A provisionally marketed tobacco product can never serve as a valid predicate tobacco product. Under section 905(j)(1)(A)(i) of the FD&C Act, SE reports may compare new products only to products that were commercially marketed as of February 15, 2007, or products that FDA has previously determined to be substantially equivalent to a predicate tobacco product. Products that are the subject of "provisional" SE Reports, though legally sold or distributed, may not serve as predicate tobacco products under the FD&C Act unless they have been previously found to be SE.

However, FDA intends to exercise enforcement discretion and not take enforcement action against a new tobacco product that is marketed without a required marketing authorization order in the following situation:[29]

- The new tobacco product has been modified to be packaged in a different quantity from, but the per weight composition is identical to, a product that is subject to a "provisional" SE Report for which FDA has not yet issued an order under section 910(a) of the FD&C Act;
- The manufacturer submits a Product Quantity Change SE Report as outlined in the response to question 18 above. The Product Quantity SE Report should identify the STN assigned by FDA for the original provisional SE Report, and provide information on the provisional product in lieu of the predicate information described in question 6; and
- The manufacturer does not commercially distribute the new tobacco product that is the subject of the Product Quantity Change SE Report until 90 days (see Section 905(j)(1)) after FDA's receipt of the complete Product Quantity Change SE Report (as outlined in the response to question 6 above); or for products already on the market as of the date of issuance of this guidance, if the manufacturer submits the complete Product Quantity Change SE Report to be received by CTP **within 30 calendar days** of the date of the issuance of the second edition of this guidance (refer to the cover page of this guidance document for date of issuance). Because this explanation was also contained in the March 2015 FAQ Guidance, FDA is in essence extending this initial 30 day period to be 30 calendar days after the issuance of the second edition of this guidance.

FDA intends to issue an order on the new tobacco product that is the subject of the Product Quantity SE Report only after it has completed its review of the "provisional" SE Report because, as explained above, products that are the subject of "provisional" SE reports may not serve as predicate tobacco products under the FD&C Act unless they have been previously found SE. Ultimately, if the product that is the subject of the

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products that are the subjects of provisional SE Reports may remain on the market unless FDA finds the products not substantially equivalent (NSE) to a predicate product.

[29] Products may be subject to enforcement at any time for other violations of the FD&C Act.

"provisional" SE Report receives an SE order, FDA intends to then issue, if appropriate, an order for the new tobacco product that is the subject of the Product Quantity Change SE Report. If the product that is the subject of the "provisional" SE Report receives a not substantially equivalent (NSE) order, FDA intends to take appropriate enforcement action if the new tobacco product that is the subject of the Product Quantity Change SE Report continues to be marketed. In sum, if the product that is the subject of the "provisional" SE Report is found NSE, then neither it nor the modified new product that is the subject of the Product Quantity Change SE Report, may be introduced or delivered for introduction into interstate commerce for commercial distribution without first obtaining a marketing order (via a different pathway or a new SE Report); doing so would render the product adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act).

Question 22:
What if I have a tobacco product that is legally sold in one quantity because it was commercially marketed as of February 15, 2007, but I have changed the quantity of product sold in a package (e.g., the number of portioned parts per package has changed such that the new product would hold 24 cigarettes per pack instead of 20; the weight of the product has changed such that the new smokeless package would change from 24 grams to 5 grams) and I am now commercially marketing that product with the product quantity change?

Response:
The tobacco product with the product quantity change is a new tobacco product subject to premarket requirements under section 910(a) of the FD&C Act. New tobacco products may not be sold or distributed in interstate commerce without an order from FDA under either section 910(c)(1)(A)(i) or section 910(a)(2)(A) of the FD&C Act. As outlined in the responses to questions 9 and 10, you may submit a Product Quantity Change SE Report, and FDA will determine whether the new tobacco product is substantially equivalent.

However, FDA does not intend to object to the commercial distribution of a new product that has a different product quantity than, but is otherwise identical to, a product that is currently being sold or distributed in interstate commerce prior to FDA's issuance of an order under section 910(a) of the FD&C Act in the following situation:

- The manufacturer submits a complete Product Quantity Change SE Report as outlined in the response to question 18 above, to be received by CTP **within 30 calendar days** of the date of issuance of the second edition of this guidance (refer to the cover page of this guidance document for the date of issuance). Because this explanation was also contained in the March 2015 FAQ Guidance, FDA is in essence extending this initial 30 day period by several months to be 30 calendar days after the issuance of the second edition of this guidance.

If, after review of the Product Quantity Change SE Report, FDA finds that the new product that is the subject of the Product Quantity Change SE Report is NSE to the

predicate tobacco product, then the compliance policy described above will no longer apply.

Question 23:
If, in addition to changing the product quantity, a manufacturer makes another change to the product, e.g., an addition of an ingredient, can both changes be addressed through a Product Quantity Change SE Report?

Response:
The Product Quantity Change SE Report is a streamlined report intended to address changes to a tobacco product where the only change is a change in quantity of product placed in a package. If you have made other changes to your new product, you should submit a full SE report that addresses all of the changes, not just the product quantity change.

Question 24:
If I change the product quantity in a portioned product (e.g., change from 0.5g to 1g sachets of moist snuff or king-size to 100s cigarettes) can I use the Product Quantity Change SE Report?

Response:
No. The Product Quantity Change SE Report is a streamlined report intended to address changes to a tobacco product where the only change is a change in quantity of product placed in a package where the per weight composition of the new and predicate product are identical. A change in portion is independent from a change in product quantity. If portion size is changed, you should submit a full SE report that addresses all of the changes, not just the product quantity change.

Question 25:
If in addition to changing the product quantity I change the name of my product, can I use the Product Quantity Change SE Report?

Response:
Yes. The Product Quantity Change SE Report would be appropriate for a new tobacco product that when compared to a predicate has a single modification in characteristics that is limited to product quantity, and may also include changes to the label that would otherwise qualify for a Same Characteristics SE report. However, if the new tobacco product has an additional modification to characteristics outside of a product quantity with identical per weight composition when compared to the predicate tobacco product, you should submit a full SE report that addresses all of the changes.

C. Additives/Specifications

This section of the guidance describes FDA's current thinking on whether and when a change to a tobacco product's additives or specifications renders that product a "new tobacco product" subject to premarket review.

Question 26:
Would a tobacco product be a "new tobacco product" subject to the substantial equivalence provisions if the tobacco product was commercially marketed as of February 15, 2007, but subsequently a new supplier was used for an ingredient, additive, component, part, or material?

Response:
It depends. If the tobacco product was commercially marketed in the United States on February 15, 2007, and subsequently a new supplier is used for the same ingredient, additive, component, part, or material with identical specifications, then this type of change would not render the tobacco product a new tobacco product. For example, if a tobacco product commercially marketed as of February 15, 2007, contained food-grade sodium carbonate from one supplier and a subsequent product was identical in every respect except that it contained food grade sodium carbonate in the same amount from a second supplier, FDA would not consider the second product to be a new product; therefore, submission of a marketing application such as an SE report would not be required.

On the other hand, if a different supplier either uses a different ingredient, additive, component, part, or material, then the product is a new tobacco product and the manufacturer must follow a regulatory pathway to market for the new product (i.e., a premarket tobacco application under 910(b), an SE Report under 905(j), or a request for an exemption from the substantial equivalence requirements under 21 CFR 1107.1). For example, the premarket requirements of sections 905(j) and 910(a) would apply if an alternate cigarette paper supplier provided paper that is more porous than the paper used in the product that was commercially marketed as of February 15, 2007. In that case, if a manufacturer chooses to submit an SE report, it should be the full report listing all characteristics of the new and predicate tobacco products.

Question 27:
Would a tobacco product be a "new tobacco product" and subject to the substantial equivalence provisions if a tobacco blending change is made to address variation in tobacco growing conditions?

Response:
At this time, FDA does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product. However, blending changes that are intended to alter the chemical or perception properties of the new product (e.g., nicotine level, pH, smoothness, harshness, etc.)

compared to the predicate product, should be reported under 910 or 905(j). If you have any questions regarding a specific tobacco blending change please contact us.[30]

Question 28:
Would a tobacco product be a "new tobacco product," and subject to the substantial equivalence provisions if the tobacco product was commercially marketed as of February 15, 2007, but subsequently a specification for an additive was tightened (i.e., narrowed) within the range of the original specification or the specification for an additive was changed (for example, from .003 to .005)?

Response:
Any modification made to the level of an additive in a product after February 15, 2007, renders the product a new tobacco product subject to one of the regulatory pathways to market (i.e., a premarket tobacco application under section 910(b), an SE Report under section 905(j), or a request for an exemption from the substantial equivalence requirements under 21 CFR 1107.1). Changes in controls on production (such as improved quality control) that would not affect the actual level of an additive in a product would not make that product a "new tobacco product" under the FD&C Act.

Question 29:
Would a cigarette be a "new tobacco product," and subject to the substantial equivalence provisions, if the cigarette was commercially marketed as of February 15, 2007, but subsequently the paper was changed to fire standard compliant (FSC) paper?

Response:
Yes. A modification made to the cigarette paper to change it to FSC paper after February 15, 2007, renders the product a new tobacco product and subject to one of the regulatory pathways to market (such as a premarket tobacco application under section 910(b) or an SE Report under section 905(j)). This is because the change to FSC paper leads to a difference in design parameters, ingredients, and/or materials, and is therefore a modification as defined under section 910(a)(1)(B) of the FD&C Act. If a manufacturer chooses to submit an SE report, it should be the full report listing all characteristics of the new and predicate tobacco products.

Question 30:
Would a tobacco product be a "new tobacco product" and subject to the substantial equivalence provisions if the tobacco product was commercially marketed as of February 15, 2007, but subsequently a supplier of a component (e.g., the filter) began using a new processing aid (e.g., an antimicrobial agent) for a subcomponent (e.g., paper used for the

[30] For additional information on meetings, please refer to the CTP guidance, "*Meetings with Industry and Investigators on the Research and Development of Tobacco Products*" (CTP Meetings Guidance) available on the Internet at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM305282.pdf.

filter's plug wrap) and the change is so minor that it is not even capable of being quantified in the finished product?

Response:
Yes. Any change in a tobacco product's composition fits the definition of a modification under section 910(a)(1)(B) of the FD&C Act and renders the product a new tobacco product. The new tobacco product would be subject to one of the regulatory pathways to market (e.g., a premarket tobacco application under section 910(b), an SE Report under section 905(j), or a request for an exemption from the substantial equivalence requirements under 21 CFR 1107.1).

D. General Questions About Section 905(j)/SE Reports

This section of the guidance responds to general questions related to the submission and review of SE Reports.

Question 31:
May companies contact the Agency to determine if certain modifications convert an existing product into a "new tobacco product" and require a substantial equivalence filing?

Response:
Yes. If you have questions regarding whether a particular change would require submission of an SE report, please contact CTP to request a meeting.[31]

Question 32:
If a company currently commercially markets the exact same tobacco product (e.g., identical composition, specifications, design features) under multiple product names, can the company make one substantial equivalence submission covering all of the products, where it: (a) includes only one list of ingredients, specifications, design features, etc.; (b) identifies all of the products that list covers; and then (c) compares that one list to a list for a predicate product?

Response:
Yes. To avoid submitting identical section 905(j) SE Reports, manufacturers may submit one SE Report for all products that are distinct because they differ only by name. However, because FDA will have to unbundle the report administratively to create separate reports for each distinct product, the manufacturer should structure the SE Report in a way that accurately compares each new tobacco product to a predicate product. The cover letter should identify all products covered in the submission, both the new tobacco products and the predicate tobacco product to which they are being compared (see, e.g., section "V.A Content/Data to Submit, Cover Letter" of the Demonstrating SE Guidance). The manufacturer may also consider the applicability of

[31] For additional information on meetings, please refer to the CTP Meetings Guidance.

the recommendations of this FAQs guidance in section II.A on Same Characteristics SE Reports.

Question 33:
How do I know whether a characteristic should be reported as a material or ingredient?

Response:
The statute defines "substantial equivalence" in terms of characteristics (section 910(a)(3)(A) of the FD&C Act). The statute also defines "characteristics" as the materials, ingredients, design, composition, heating source, or other features of a tobacco product (section 910(a)(3)(B) of the FD&C Act). However, the statute does not further define each of the terms used in the definition of "characteristics." The Demonstrating SE Guidance provides recommendations related to characteristics (http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf). In general, in preparing your SE Report, it is important that your comparison to a predicate include all characteristics. FDA recognizes that you may be uncertain of the category (e.g., material or ingredient) in which a particular characteristic best fits. For purposes of comparison, it is important that characteristics be reported in the same category for both the new tobacco product and the predicate. FDA will review your submission as a whole and consider the totality of the data presented when making FDA's determination of substantial equivalence. You may also consider requesting a meeting with CTP.[32]

Question 34:
Glue is not listed as an example of a component, part, or accessory of a tobacco product in the Demonstrating SE Guidance. Is glue considered a component, part or accessory such that a change in the glue might render a product a new tobacco product subject to the substantial equivalence provisions?

Response:
It depends. For purposes of substantial equivalence, the characteristics of the new tobacco product should be compared to the characteristics of a predicate. Characteristics means the materials, ingredients, design, composition, heating source, or other features of the tobacco product. If the glue is modified in a tobacco product after February 15, 2007, the product is a new tobacco product and is subject to premarket review (e.g., a premarket tobacco application under section 910(b) or SE Report under section 905(j)). As discussed in more detail in the Demonstrating SE Guidance, for unfinished products (including products where glue is a component, part or accessory), FDA intends to limit its enforcement of the requirements of sections 910 and 905(j) of the FD&C Act to the finished, regulated products. To avoid the submission of duplicative information, FDA does not at this time intend to enforce the requirements of 910 and 905(j) for components, parts or accessories of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products. We anticipate receiving all relevant information regarding such new tobacco products in the 905(j) reports of the finished

[32] For additional information on meetings, please refer to the CTP Meetings Guidance.

regulated tobacco products. It is therefore the finished product manufacturer's responsibility to ensure it has accurate information regarding the components, parts and accessories included in its product. The manufacturer must obtain appropriate market authorization for any changes to a tobacco product, including modifications to components, parts, or accessories.

Question 35:
How should harmful and potentially harmful constituents (HPHCs) be reported in my SE Report?

Response:
It is an applicant's responsibility to provide appropriate scientific evidence and data if FDA is to make a finding that the predicate and new products are substantially equivalent. Reporting quantities of HPHCs in predicate and new products is a useful mechanism for manufacturers to demonstrate that the differences in characteristics between the predicate and new products do not cause the new products to raise different questions of public health within the meaning of 910(a)(3)(A)(ii) of the FD&C Act. When providing HPHCs in an SE Report, they should be appropriate for the type of tobacco product (e.g., cigarette, smokeless, etc.) and predicate product used for comparison. For example, when submitting an SE Report for a change to FSC paper in a cigarette after February 15, 2007, many manufacturers have provided information for TNCO (tar, nicotine, and carbon monoxide) as this type of modification may change TNCO. However, for this FSC example you may not need to include information about aflatoxin B1 in your SE Report as it is not expected to change due to this modification.

If you have additional questions regarding reporting of HPHCs in your SE Report and would like to discuss your questions with the Agency, please contact CTP to request a meeting.[33]

Question 36:
Do I need to submit an environmental assessment as part of my section 905(j) SE Report?

Response:
Yes. FDA's regulations implementing the National Environmental Policy Act (NEPA) of 1969 require that "[a]ll applications or petitions requesting agency action require the submission of an [environmental assessment] or a claim of categorical exclusion" (21 CFR 25.15(a)). Currently, there are no categorical exclusions in place for tobacco products;[34] therefore, manufacturers submitting applications or reports for any of the three regulatory pathways (including reports under section 905(j)) must include environmental assessments as part of their submissions. You should refer to 21 CFR part 25 for additional information. If you have questions regarding what you should include

[33] For additional information on meetings, please refer to the CTP Meetings Guidance.
[34] On January 23, 2014, FDA issued a proposed rule that, if finalized, would provide categorical exclusions for certain actions, including actions related to substantial equivalence (SE) reports (79 Federal Register 3742).

in your environmental assessment, and would like to discuss your questions with the Agency, please contact CTP to request a meeting.[35]

[35] Please refer to the CTP Meetings Guidance.

APPENDIX 1.

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Same Characteristics SE Report

To whom it may concern:

Mock-Up Tobacco Company respectfully submits a Same Characteristics SE Report for the new product, Cable Car Cigarettes. The predicate tobacco product, Seabreeze Cigarettes, is a grandfathered tobacco product as it was commercially marketed in the United States as of February 15, 2007. Enclosed within our application you will find all materials requested pursuant to your final SE FAQ guidance.

Respectfully submitted,

John Doe
Vice President
Mock-Up Tobacco Company

APPENDIX 2.

SAME CHARACTERISTICS SE REPORT

I. Full identification of the new tobacco product:

- **Manufacturer:** Mock-Up Tobacco Company
- **Unique name:** Cable Car
- **Product category:** Cigarette
- **Product subcategory:** Combusted, filtered
- **Package type:** Box
- **Package quantity:** 20
- **Length:** 100 mm
- **Diameter:** 8.1 mm
- **Ventilation:** 35%
- **Characterizing Flavor:** none

II. Full identification of the predicate tobacco product:

- **Manufacturer:** Mock-Up Tobacco Company
- **Unique name:** Seabreeze
- **Product category:** Cigarette
- **Product subcategory:** Combusted, filtered
- **Package type:** Box
- **Package quantity:** 20
- **Length:** 100 mm
- **Diameter:** 8.1 mm
- **Ventilation:** 35%
- **Characterizing Flavor:** none
- This product was commercially marketed in the United States as of February 15, 2007. The evidence to support this is located in Attachment A.[36]

III. If have previously submitted an SE report, provide Submission Tracking Number (STN):

- None – I have not previously submitted an SE Report for this product

IV. Statement of whether Mock-Up Tobacco Company intends to commercially distribute both the predicate and new tobacco product, or only the new tobacco product:

[36] Please note that any reference to an "Attachment" in this example is illustrative only and intended to demonstrate how a manufacturer might explain where the evidence or other supportive information may be found in their SE Report.

- Mock-Up Tobacco Company intends to market both the new and predicate tobacco products.

V. Environmental Assessment: Located in Attachment B

VI. Health Information Summary or Health Information Statement:

- A Health Information Summary will be made available upon request by any person.

VII. Statement of action to comply with the requirements under section 907 of the FD&C Act:

- Our new product complies with the requirements under section 907 of the FD&C Act. This new product does not contain a characterizing flavor as described in section 907(a)(1)(A). Additionally, we will continue to comply with the applicable standards under section 907 of the Act including those standards under section 907(a) and any promulgated through regulation.

VIII. **Certification Statement:**

- I, John Doe, Vice President of Mock-Up Tobacco Company, on behalf of Mock-Up Tobacco Company, certify that Cable Car Cigarettes has a different name on the label from Seabreeze cigarettes but is otherwise identical to Seabreeze Cigarettes. I certify that Mock-Up Tobacco Company understands this means there is no modification, except for the different name on the label from the predicate tobacco product, including any change in materials, ingredients, design features, heating source, or any other features. I certify that this information and the accompanying submission are true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Signed,

John Doe, Vice President

Revisions. This is a revision to the first edition of this guidance, which FDA issued March 4, 2015 (FDA added an interim enforcement policy note to the first edition in May 2015 while it considered new comments to the first edition). Revisions include:

*The addition of background information to the introduction section, including a section on the submission and review of an SE Report;
*The insertion of new questions/responses and the addition of information in responses throughout section II (Responses to Frequently Asked Questions) on FDA's current thinking on label changes and product quantity changes;
*The addition of information on the additional properties needed to identify a product;
*The addition of two appendices.