

# Guidance for Industry

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

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](mailto: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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## **Guidance for Industry<sup>1</sup>**

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

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

## **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. After carefully reviewing and considering comments and information submitted in response to the draft guidance,<sup>2</sup> which covered a range of topics on demonstrating the substantial equivalence of a new tobacco product, FDA is finalizing this guidance on many of the topics. In addition, this guidance explains that a manufacturer may submit streamlined SE reports for certain modifications to labels and changes to product quantity. In reviewing this guidance, please note the following information:

- In general, a tobacco product manufacturer must submit a premarket application and obtain a marketing authorization order before the manufacturer may introduce a new tobacco product into interstate commerce (section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (21 U.S.C. 387j)).

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<sup>1</sup> This guidance was prepared by the Office of Science and Office of Regulations in the Center for Tobacco Products at FDA.

<sup>2</sup> The notice of availability for the draft guidance published on September 9, 2011 (76 Federal Register 55927).

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- 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 a substantial equivalence report (SE Report) 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.<sup>3</sup>
- 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.

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. RESPONSES TO FREQUENTLY ASKED QUESTIONS**

This section provides our responses to questions that you have asked us on the substantial equivalence provisions. Many of the questions use the term "new tobacco product." Rather than repeat the definition in every response, FDA provides the definition here, and you should refer back to it as necessary.

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<sup>3</sup> Please refer to the guidance for industry and FDA staff, *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>.

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The term *new tobacco product* means:

- 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.

(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).

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 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. Label Changes**

In the draft of this guidance issued September 2011, 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 guidance, FDA has carefully reconsidered this policy.

We have concluded that a label is not a “part” of the tobacco product.<sup>4</sup> FDA does conclude, however, 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, the modified product 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.

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<sup>4</sup> Please note that the misbranding provisions of section 903 of the FD&C Act, including the provision that states a tobacco product shall be deemed to be misbranded if its labeling is false or misleading in any particular, continue to apply to all tobacco products subject to FDA’s Chapter IX authorities.

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Whether a product with a label change results in a distinct product depends on the circumstances. Some types of changes that might result in a distinct product are changes to logo, identifiable patterns of color, product descriptors, or any combination thereof. One consideration would be whether the label change would lead consumers to believe that the product is different from the predicate. Therefore, 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. This interpretation is consistent with provisions throughout the FD&C Act, in which individual tobacco products are distinguished primarily on the basis of brands<sup>5</sup> and subbrands.<sup>6</sup> If a product is new because it is distinct, but the product has the same characteristics as the predicate tobacco product, then the manufacturer or importer may opt to submit a “Same Characteristics SE Report”<sup>7</sup> (e.g., the name or logo of the tobacco product is modified in a way that makes it distinct) as discussed in more detail in the following questions and answers.

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. This chart provides some basic examples.

<b>Label Change</b>	<b>Examples that May Result in a Distinct Product</b>	<b>Examples that May Not Result in a Distinct Product</b>
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

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<sup>5</sup> Section 900(2) of the FD&C Act (21 U.S.C. 387(2)) 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.”

<sup>6</sup> For example, sections 904 and 915 of the FD&C Act (21 U.S.C. 387d and 387o) require reporting of ingredient information and HPHCs by brand and subbrand. This position is also reflected in another guidance interpreting section 905. Specifically, the guidance for industry *Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments* states that “[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>).

<sup>7</sup> As described in this section, the Same Characteristics 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.



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### **Question 1:**

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 is a modification that makes the product distinct. Therefore, the modified 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 3. 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 2:**

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), what information should I submit to demonstrate substantial equivalence?

### **Response:**

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 an SE Report that contains a brief, specific set of information (Same Characteristics SE Report). We believe 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 and, therefore, FDA expects to review these reports more quickly. FDA intends to review these in a queue separate from 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 3:**

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.**”

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- Full identification of your new tobacco product:<sup>8</sup>
  - 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 CTP to request a meeting<sup>9</sup> 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).
- Full identification of a predicate tobacco product:<sup>10</sup>
  - 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).
- 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 market both the predicate tobacco product and the new tobacco product, or only the new tobacco product (please also see the response to question 7).
- Environmental Assessment (please also see the response to question 26).
- 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).

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<sup>8</sup> 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).

<sup>9</sup> 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.

<sup>10</sup> The predicate tobacco product 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.



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- 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”).
- 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] 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 4:**

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 5:**

What if I wish to modify my tobacco product in a way that makes it distinct if my product is the subject of a “provisional”<sup>11</sup> SE Report that is pending review at FDA?

#### **Response:**

Under section 905(j)(1)(A)(i) of the FD&C Act, SE reports may compare the new product to only 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, while 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.

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<sup>11</sup> 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.

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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 subject to a “provisional” SE Report 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 3 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 3; and
- The manufacturer does not commercially market the product until 90 days after FDA’s receipt of the complete Same Characteristics SE Report (as outlined in the response to question 3 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 this guidance (refer to the cover page of this guidance document for date of issuance).

FDA intends to issue its order on the product that is distinct only after it has completed its review of the original “provisional” SE Report because, as stated, 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 original “provisional” SE Report is found substantially equivalent to a predicate tobacco product, FDA intends to issue a subsequent order for the product with the modification. If the product that is the subject of the original “provisional” SE Report is found not substantially equivalent (NSE) to the predicate tobacco product, then the compliance policy described above will no longer apply. If the original “provisional” SE Report is found NSE, neither the product subject to the original provisional report, nor the product that is distinct, may be introduced or delivered for introduction into interstate commerce for commercial distribution; doing so would render the product adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act; 21 U.S.C. 387b(6)(A), 387c(a)(6)). We note that all products on the market, including the products identified in this response, are subject to enforcement at any time for violations of the FD&C Act.

#### **Question 6:**

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 product with that change?

#### **Response:**

The tobacco product with the modified label 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

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the responses to questions 2 and 3, you may submit a Same Characteristics SE Report for a label change, 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 3 above, to be received by CTP **within 30 calendar days** of the date of issuance of this guidance (refer to the cover page of this guidance document for the date of issuance).

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 section 902(6) and 903(a)(6) of the FD&C Act.

### **Question 7:**

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 3. The Same Characteristics SE Report should indicate whether the manufacturer intends to commercially market the product both as Brand X and Brand Y.

## **B. Product Quantity Changes**

FDA has determined that the introduction of a product for which the product quantity in the package<sup>12</sup> 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

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<sup>12</sup> For example, the pack, box, carton, container, or wrapping (such as cellophane), in which a tobacco product is sold to consumers.

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grams to 5 grams), even if the per weight composition<sup>13</sup> 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) have changed.

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”<sup>14</sup> as discussed in more detail in the following questions and answers.

### **Question 8:**

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 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 10).

### **Question 9:**

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), what information should I submit to demonstrate substantial equivalence?

### **Response:**

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

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<sup>13</sup> The manner in which the materials (e.g., ingredients, additives, and biological organisms) are arranged and integrated to produce a finished tobacco product.

<sup>14</sup> 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.

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commercially marketed as of February 15, 2007, or a product that has been found by FDA to be substantially equivalent, you may submit an 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. 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 10:**

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:<sup>15</sup>
  - 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)
  - package type (e.g., soft pack, box, plastic can with metal lid, bag).
- Full identification of a predicate tobacco product:<sup>16</sup>
  - manufacturer,

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<sup>15</sup> The new tobacco product is the tobacco product that has a different product quantity, but the per weight composition inside the package is unchanged.

<sup>16</sup> 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.

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- 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).
- 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 market 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 26).
- 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*



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*company] understands this means there is no 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 11:**

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 12:**

Can I change the quantity of product sold in a package if the product is the subject of a “provisional”<sup>17</sup> SE Report that is pending review at FDA?

### **Response:**

Under section 905(j)(1)(A)(i) of the FD&C Act, SE reports may compare the new product to only 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, while 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 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 subject to a “provisional” SE Report 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 Product Quantity Change SE Report as outlined in the response to question 10 above. The Product Quantity Change SE Report should identify the STN assigned by FDA for the original provisional SE Report,

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<sup>17</sup> 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.

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- and provide information on the provisional product in lieu of the predicate information described in the response to question 10; and
- The manufacturer does not commercially market the product until 90 days after FDA's receipt of the complete Product Quantity Change SE Report (as outlined in the response to question 10 above); or for products with a changed product quantity 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 this guidance (refer to the cover page of this guidance document for date of issuance).

FDA intends to issue its order on the product with the changed product quantity only after it has completed its review of the original "provisional" SE report because, as stated, 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 original "provisional" SE Report is found substantially equivalent to a predicate tobacco product, FDA intends to issue a subsequent order for the product with the modification. If the product that is the subject of the original "provisional" SE Report is found not substantially equivalent (NSE) to the predicate tobacco product, then the compliance policy described above will no longer apply. If the original "provisional" SE Report is found NSE, neither the product subject to the original provisional report, nor the product with the modification, may be introduced or delivered for introduction into interstate commerce for commercial distribution; doing so would render the product adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act; 21 U.S.C. 387b(6)(A), 387c(a)(6)). We note that all products on the market, including the products identified in this response, are subject to enforcement at any time for violations of the FD&C Act.

#### **Question 13:**

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.

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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 10 above, to be received by CTP **within 30 calendar days** of the date of issuance of this guidance (refer to the cover page of this guidance document for the date of issuance).

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 14:**

If, in addition to changing the product quantity, a manufacturer makes another change to the product, e.g., a name change or a change in design, can both changes be addressed through a Product Quantity Change SE Report?

#### **Response:**

The Product Quantity Change SE Report is a streamlined report only intended to address changes 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 15:**

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 only intended to address changes in quantity of product placed in a package. 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.

### *C. Additives/Specifications*

#### **Question 16:**

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?

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### **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 17:**

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.<sup>18</sup>

### **Question 18:**

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)?

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<sup>18</sup> For additional information on meetings, please refer to the CTP Meetings Guidance.

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### **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 19:**

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 20:**

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 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).

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

#### **Question 21:**

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.<sup>19</sup>

#### **Question 22:**

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

#### **Question 23:**

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

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<sup>19</sup> 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>.



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### **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.

### **Question 24:**

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 one of the pathways for legal commercial marketing in the United States (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 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.

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### **Question 25:**

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.<sup>20</sup>

### **Question 26:**

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;<sup>21</sup> therefore, manufacturers submitting applications or reports for any of the three regulatory pathways to commercially market a new tobacco product (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 in your environmental assessment, and would like to discuss your questions with the Agency, please contact CTP to request a meeting.<sup>22</sup>

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<sup>20</sup> For additional information on meetings, please refer to the CTP Meetings Guidance.

<sup>21</sup> 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).

<sup>22</sup> Please refer to the CTP Meetings Guidance.