Guidance for Industry

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

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/Labeling/RulesRegulationsGuidance/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 third edition of this guidance, which FDA issued on December 12, 2016. A summary of the revisions are listed at the end of the guidance.

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Guidance for Industry[1]

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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) has received from manufacturers and other interested stakeholders (you) on demonstrating the substantial equivalence (SE) of a new tobacco product. Among other things, this guidance includes information on FDA's current thinking on whether a change to the product quantity in the package renders a product "new" and thus subject to premarket review.

FDA is issuing this revised final guidance following a decision by the United States District Court for the District of Columbia.[2] The court found that "a modification to an existing product's label does not result in a 'new tobacco product.'"[3] Accordingly, manufacturers need not receive premarket authorization for existing products that are the

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

[2] The previous version of this guidance published September 8, 2015 (80 Federal Register 53810). Please note that in this current version of the guidance, FDA refers to "SE Reports" as "SE applications," but the terms both refer to a premarket submission under section 905(j)(1)(A) of the FD&C Act.

[3] *Philip Morris USA Inc. v. United States Food and Drug Administration*, ___F. Supp. 3d___, No. 15-cv1590 (APM), 2016 WL 4378970 (D.D.C. Aug. 16, 2016).

subject of a label change only (e.g., a product that has a new name but is otherwise identical to the predicate) (see also question 17).[4]

This guidance continues to provide recommendations related to SE applications for product quantity changes. This is consistent with the court's finding that a change to an existing product's quantity does result in a "new tobacco product." The guidance explains that a manufacturer may submit a streamlined SE application for certain changes to product quantity as an alternative to the more comprehensive (full) SE application. The guidance also explains FDA's plans and processes for review of the streamlined SE applications. 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 Federal Food, Drug, and Cosmetic Act (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 application 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.

[4] Please note, however, that certain changes to tobacco products should be submitted to FDA as part of a domestic tobacco product establishment's biannual updates to its product listing under section 905(i)(3) of the FD&C Act. For more information, please see "Registration and Product Listing for Owner and Operators of Domestic Tobacco Product Establishments, Guidance for Industry" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments).

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) an application 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) of the FD&C Act.

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, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). This term does not mean an article that under the FD&C Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food (section 201(f)) if the food contains no nicotine, or no more than trace amounts of naturally occurring nicotine (see section 201(rr) of the FD&C Act).

C. Submission and Review of an SE Application

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 application, 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 SE application (section 905(j)(1)). FDA published the final rule *Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports* (SE final rule) on October 5, 2021, to provide additional clarity on the content and format of information that must be included in a full SE application 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).

This guidance provides information and clarifies FDA's recommendations with respect to the data and information to be included in a streamlined same characteristics SE Application for product quantity changes, referred to in this guidance as "Product Quantity Change SE Applications." As discussed further below, manufacturers must provide the applicable required information set out in section 1107.18 of the SE final rule in these applications, but such applications would be required to include less comparison information than that described in section 1107.19. Thus, these applications should be easier for industry to prepare and for FDA to review than full SE applications.[5] FDA is also adopting processes and procedures to better enable the agency to review these streamlined applications expeditiously, including placing them in separate queues from full SE applications.

III. 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

[5] Information that manufacturers might use to show pre-existing tobacco product status is discussed in the guidance document entitled, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007). Additional information on preparing environmental assessments is provided at 21 CFR part 25.

the 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. Product Quantity Changes

This section of the guidance describes FDA's current thinking on whether 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 identical (i.e., identical per weight composition, design features, heating source, and other features of the product), and explains FDA's plans for review of such submissions.

Question 1:
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[6] 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[7] 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) 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.

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.

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

However, we have determined that changes to product quantity (when all other product characteristics remain identical) 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 Application"[8] as discussed in more detail in the following questions and answers.

Question 2:
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 Application as an alternative to a full (more detailed) SE application or premarket application under section 910(b) of the FD&C Act (as discussed in the response to question 5).

Question 3:
What purpose is served by the submission of the Product Quantity Change SE Applications?

Response:
As discussed in the response to question 1, the Product Quantity Change SE Application 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 of the FD&C Act). 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.

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

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 the Tobacco Control Act; 21 CFR 1140.14(d)). 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. Product Quantity Change SE Applications involve modifications that result in the new tobacco product having different characteristics from the predicate tobacco product.

Application is intended to provide manufacturers with a more limited and less burdensome application 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 Applications 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.[9] Larger product quantities can potentially reduce cessation behaviors and increase tobacco product use among current users.[10] 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.

Question 4:
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 application that contains all of the comparison information required by section 1107.19 of the SE final rule?

Response:
No. Section 905(j) authorizes the agency to determine the form and manner of the SE application. FDA has determined that, if you have a tobacco product that is provided in a different quantity, but is otherwise identical (i.e., identical per weight composition, design features, heating source, and other features of the product) to either a tobacco

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[9] 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.

[10] Wertenbroch, K. (1998). Consumption self-control by rationing purchase quantities of virtue and vice. Marketing Science, 17, 317-337.

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 Product Quantity Change SE Application that contains a brief, specific set of information as set out in section 1107.18 of the SE final rule. This applies 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.

Less material is required by the SE final rule for a Product Quantity Change SE Application than for a full SE application. We believe the information included in the Product Quantity Change SE Application should be sufficient for FDA to make its SE determination in this situation. This Product Quantity Change SE Application should be easier for industry to prepare and for FDA to review than would typically be the case for SE applications involving other changes to a tobacco product and, therefore, FDA expects to review these applications more quickly. More information related to the Product Quantity Change SE Application is provided in the following questions and responses.

Question 5:
What information should a Product Quantity Change SE Application contain?

Response:
An SE Report submitted under the same characteristics prong as a Product Quantity Change SE Application must contain the applicable required information set out in 1107.18, but would not need to include the comparison information as set out in 1107.19.

Question 6:
How will FDA review Product Quantity Change SE Applications?

Response:
There are far fewer materials and information to be submitted in a Product Quantity Change SE Application than a full SE application, 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 review of a full SE application generally. FDA intends to review Product Quantity Change SE Applications in a queue separate from SE applications 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[11] for issuance of a decision to a Product Quantity Change SE Application.

Question 7:
If I currently have an SE application pending with FDA, may I use the Product Quantity Change SE Application instead?

Response:
If your pending application 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

[11] A review cycle ends with an action letter, e.g., a preliminary finding letter, 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.

Product Quantity Change SE Application for the new product, or if this is to a provisional SE Application, you may amend your pending application with all the information to support the product quantity change.

Question 8:
Can I change the quantity of product sold in a package if the product is the subject of a "provisional"[12] SE application that is pending review at FDA?

Response:
A provisionally marketed tobacco product can not serve as a valid predicate tobacco product unless FDA issues an order finding it SE. Under section 905(j)(1)(A)(i) of the FD&C Act, SE applications 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 applications, 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:[13]

- 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 Application for which FDA has not yet issued an order under section 910(a) of the FD&C Act;
- The manufacturer submitted a Product Quantity Change SE Application similar to the situation outlined in the response to question 4 above.[14]
- The Product Quantity Change SE Application should identify the STN assigned by FDA for the original provisional SE application, and provide information on the provisional product in lieu of the predicate information; and
- The manufacturer does not commercially distribute the new tobacco product that is the subject of the Product Quantity Change SE Application until 90 days (see Section 905(j)(1)) after FDA's receipt of the complete Product Quantity Change SE Application.

[12] A "provisional" SE application 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 applications may remain on the market unless FDA finds the products not substantially equivalent (NSE) to a predicate product.
[13] Products may be subject to enforcement at any time for other violations of the FD&C Act.
[14] If the manufacturer submitted a complete Product Quantity Change SE Application by October 8, 2015, for a product already on the market as of September 8, 2015, FDA does not intend to object to the commercial distribution of the new tobacco product while the application is under review (as provided in the second edition of the FAQs guidance, issued September 8, 2015). If the product that is the subject of the "provisional" SE application receives a not substantially equivalent order, or, if after review of the Product Quantity Change SE Application FDA finds that the new product that is the subject of the Product Quantity Change SE Application is NSE to the predicate tobacco product, then such compliance policy will no longer apply.

FDA intends to issue an order on the new tobacco product that is the subject of the Product Quantity Change SE Application only after it has completed its review of the "provisional" SE application because, as explained above, products that are the subject of "provisional" SE applications 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 application 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 Application. If the product that is the subject of the "provisional" SE Application 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 Application continues to be marketed. In sum, if the product that is the subject of the "provisional" SE application is found NSE, then neither it nor the modified new product that is the subject of the Product Quantity Change SE Application, 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 application); doing so would render the product adulterated and misbranded (sections 902(6)(A) and 903(a)(6) of the FD&C Act).

Question 9:
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.[15] 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 4 and 5, you may submit a Product Quantity Change SE Application, and FDA will determine whether the new tobacco product is substantially equivalent. See also the responses to questions 7 and 8.

Question 10:
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 Application?

[15] As described in the response to question 8, if the manufacturer submitted a complete Product Quantity Change SE application by October 8, 2015, for a product already on the market as of September 8, 2015, FDA does not intend to object to the commercial distribution of the new tobacco product while the application is under review (as provided in the second edition of the FAQs guidance, issued September 8, 2015). If, after review of the Product Quantity Change SE Application, FDA finds that the new product that is the subject of the Product Quantity Change SE Application is NSE to the predicate tobacco product, then such compliance policy will no longer apply.

Response:
The Product Quantity Change SE Application is a specific type of same characteristics SE Report intended to address limited changes to a tobacco product. It is always your responsibility to decide whether multiple changes to a new tobacco product warrant a same characteristics or different characteristics SE Report. Examples of changes that are likely to be appropriate to proceed as same characteristics at this time include:

- A change in product quantity between the new and predicate tobacco products
- A change in container closure system between the new and predicate non-moist tobacco products (e.g., soft pack to hard pack of cigarettes)
- A change in container closure system between the new and predicate non-moist tobacco products where the same material is being used (*e.g.,* change from one plastic container to another plastic container, change from one metal container to another metal container) and there is no difference in flavors being added to the container closure systems that would change the characterizing flavor
- For moist tobacco products, a change in container closure system between the new and predicate tobacco products from one type of plastic to another similar type of plastic where there is no difference in flavors being added to the container closure systems that would change the characterizing flavor and no difference in size of the container closure system
- A change to a lower amount of total tobacco in the new tobacco product without any corresponding changes in other ingredients or characteristics in the new tobacco product
- A change in tipping paper color from plain to cork where the target specifications of the tipping paper are identical
- A change in adhesive in the non-combusted portion of a cigarette
- The replacement of one filter tow with an alternate filter tow with identical target specifications (e.g*.,* vendor specifications, measured values for denier per filament, total denier)
- The removal of a dye or ink from the non-combusted portion of a tobacco product or removal of printed monogram ink from the barrel of a cigarette
- A change to replace a lower grade version of an ingredient with an equal quantity of a higher grade version of the same ingredient (e.g., replacing nicotine with USP grade nicotine)
- A change to remove a single flavor ingredient, including a complex ingredient, in the new tobacco product compared to the predicate or removing an ingredient in the predicate tobacco product and replacing that ingredient with an equal quantity of water in the new tobacco product
- For combusted tobacco products, a change in the pattern of non-ink watermark on papers or wrappers, provided the papers or wrappers have identical target specifications and the change does not alter or affect the design parameters of the paper/wrapper
- For combusted tobacco products, a change from one paper or wrapper to a similar paper or wrapper from an alternate supplier that do not impact HPHC yields
- A change between a new and predicate tobacco product that results in a removal of characterizing flavor (e.g., removal of menthol from cigarettes, or removal of cherry flavor in smokeless tobacco), as well as removal of a flavor

from a component of a finished tobacco product (*e.g.,* removal of vanilla flavored adhesive in cigars and replacement with a non-flavored adhesive)
- A change in inert tip material (e.g., replacing a wood tip with a plastic tip on a cigar)
- A change from non-Fire Standard Compliant (FSC) paper to FSC paper (also known as low ignition propensity paper)
- A change from one FSC paper to an alternate FSC paper
- An absolute increase or decrease in ventilation of 11 percent or less between the new and predicate tobacco product

Question 11:
If I change the product quantity and portion size in a portioned product (e.g., change from 0.5g to 1g sachets of moist snuff or king-size to 100s cigarettes) or just the portion size in a portioned product, is this appropriate for a Product Quantity Change SE Application?

Response:
No. The Product Quantity Change SE Application is 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 size is independent from a change in product quantity and may raise different questions of public health. If portion size is changed, you should submit a full SE application that addresses all of the changes, not just the product quantity change.

B. 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 12:
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 as of 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 application 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 application 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 application, it should be the full application listing all characteristics of the new and predicate tobacco products.

Question 13:
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) compared to the predicate product, should be reported under sections 910 or 905(j). If you have any questions regarding a specific tobacco blending change please contact us.[16]

Question 14:
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 Application 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.

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[16] 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) (July 2016) available on the Internet at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/meetings-industry-and-investigators-research-and-development-tobacco-products-revised. This guidance provides information on how to request a meeting, along with recommendations about what to include in a request, etc.

Question 15:
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 application 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. However, given that cigarettes and other combusted tobacco products have historically been a leading cause of fire deaths and fire-related injuries, FDA's current thinking is that if the only change in a new combusted tobacco product is the change to FSC paper, the new product incorporating FSC paper is unlikely to raise different questions of public health as compared to the non-FSC predicate product. Consequently, as described in the response to question 10, such a new tobacco product may be appropriate to submit as a same characteristics SE Report.

Question 16:
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 application under section 905(j), or a request for an exemption from the substantial equivalence requirements under 21 CFR 1107.1).

C. Other Questions About Section 905(j)/SE Applications

This section of the guidance responds to other questions related to the submission and review of SE applications.

Question 17:
Does a change in a product label render an existing tobacco product a "new tobacco product" subject to the premarket review provisions of the FD&C Act?

Response:
No, a modification to an existing tobacco product's label, standing alone, does not result in a new tobacco product subject to the premarket review provisions of the FD&C Act. This position is consistent with a decision of the U.S. District Court for the District of Columbia (see *Philip Morris USA Inc. v. United States Food and Drug Administration*, ___F. Supp. 3d___, No. 15-cv1590 (APM), 2016 WL 4378970 (D.D.C. Aug. 16, 2016)).

Question 18:
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 application, please contact CTP to request a meeting.[17]

Question 19:
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). The SE final rule continues to include the statutory definition of substantial equivalence, and does not include codified definitions of "same characteristics" or "different characteristics." FDA intends to further consider the scope of these terms and will undertake further notice and comment rulemaking before moving to further define any of these terms by regulation. 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.[18]

Question 20:
How should harmful and potentially harmful constituents (HPHCs) be reported in my SE application?

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 necessary 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.

[17] For additional information on meetings, please refer to the CTP Meetings Guidance.
[18] As noted, please refer to the CTP Meetings Guidance.

When providing HPHCs in an SE application, they should be appropriate for the type of tobacco product (e.g., cigarette, smokeless) and predicate product used for comparison. For example, when submitting an SE application 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 application as it is not expected to change due to this modification. See section 1107.19(d) of the SE final rule for information to include for HPHCs for your new and predicate products. We also recommend that you consider the final guidance "'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act."[19]

If you have additional questions regarding reporting of HPHCs in your SE application and would like to discuss your questions with the Agency, please contact CTP to request a meeting.[20]

Question 21:
Do I need to submit an environmental assessment as part of my section 905(j) SE application?

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)). Manufacturers submitting applications or reports for any of the three regulatory pathways (including reports under section 905(j)) must include environmental assessments or a valid claim of categorical exclusion, if applicable, as part of their submission.[21]

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.[22]

[19] https://www.fda.gov/media/80109/download
[20] For additional information on meetings, please refer to the CTP Meetings Guidance.
[21] On September 24, 2015, FDA issued a final rule providing categorical exclusions for certain actions, including actions related to substantial equivalence (SE) applications (80 Federal Register 57531) (codified at 21 CFR 25.35).
[22] Please refer to the CTP Meetings Guidance.

IV. DOCUMENT HISTORY

March 2015. Original final guidance is published (the notice of availability published on March 5, 2015; 80 Federal Register 12011).

May 2015. FDA added an interim enforcement policy note to the guidance while the Agency considered new comments.

September 2015. The second edition of the guidance is published (the notice of availability published on September 8, 2015; 80 Federal Register 53810). Revisions included:

- Removal of the interim enforcement policy note;
- 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.

December 2016. The third edition of the guidance is published. Revisions include:

- The addition of information on the U.S. District Court for the District of Columbia's decision in *Philip Morris USA Inc. v. United States Food and Drug Administration*,____F. Supp. 3d____, No. 15-cv1590 (APM), 2016 WL 4378970 (D.D.C. Aug. 16, 2016)).
- The deletion of questions/responses related to SE Applications for label/name changes; the addition of one clarifying question on whether a label change to an existing product results in a new tobacco product; the renumbering of remaining questions; and, as needed, related edits and clarifications in the responses to other questions;
- Deletion of an expired enforcement discretion policy (the policy had provided a 30-day period to submit certain SE applications for new tobacco products that had proceeded to market without first obtaining marketing authorization);
- An update to reflect the final rule status of the categorical exclusions rulemaking (related to NEPA); The deletion of two appendices.

March 2023. Revisions include:

- The definition of "tobacco product" is updated to reflect statutory amendments made by the Consolidated Appropriations Act, 2022 (Pub. L. 117-103). Among other things, the legislation amends the definition of "tobacco product" in section 201(rr) of the FD&C Act to include products "containing nicotine from any source."

October 2023. Revisions include:

- Replaced "grandfathered" with "pre-existing tobacco product." to be consistent with 21 CFR 1100.202.
- Minor clarifying and editorial changes to promote consistency throughout our guidances.
- Added citations to the SE final rule, where appropriate.