FINAL GUIDANCE: SUBSTANTIAL EQUIVALENCE, RESPONSES TO FREQUENTLY ASKED QUESTIONS

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OUTLINE

- New Final Guidance
  - Overview
  - Types of SE Submissions
- Same Characteristics SE Report
  - Eligibility
  - Content
  - Submitting a New Report or Amending Pending Reports
- Product Quantity Change SE Report
  - Eligibility
  - Content
  - Submitting a New Report or Amending Pending Reports
- Comparisons Between Types of SE Reports

FINAL GUIDANCE: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS

FINAL SUBSTANTIAL EQUIVALENCE GUIDANCE

- Issued March 4, 2015
- After carefully reviewing and considering comments and information submitted in response to the draft September 2011 guidance, FDA is finalizing this guidance.
  - Most of the questions and responses to the sections on additives/specifications and general questions remain unchanged
- New items in guidance:
  - FDA concludes a label is not a part of a tobacco product
  - Discusses two new types of SE Reports that should be easier for industry to prepare and for FDA to review

FINAL SUBSTANTIAL EQUIVALENCE GUIDANCE

- This guidance concludes that a label is not part of a tobacco product.
  - This reverses the position in the draft September 2011 guidance
- A label is not the package or packaging
- Certain Changes to the label will create a new tobacco product even if the tobacco product's characteristics remain the same:
  - If modified in a way that renders the product distinct from the unmodified version
  - If a label change renders the product distinct, the change will result in a new tobacco product due to the fact the newly distinct product was not commercially marketed in the United States as of February 15, 2007 (section 910(a)(1)(A) of the FD&C Act)

FINAL SUBSTANTIAL EQUIVALENCE GUIDANCE

- Explains two additional types of SE Reports (in addition to the traditional, full SE Report):
  - Same Characteristics SE Report
  - Product Quantity Change SE Report
- In order to receive an order finding the new tobacco product substantially equivalent with respect to the predicate tobacco product, each type of SE Report must meet the requirements in the FD&C Act
- If the modification falls under the category for a same characteristics or a product quantity change SE Report, FDA has determined that a brief set of information should be sufficient for FDA to make its SE determination

SAME CHARACTERISTICS SE REPORT

SAME CHARACTERISTICS SE REPORT– LABEL MODIFICATION THAT CREATES A NEW TOBACCO PRODUCT

- If the product's label is modified in any way that renders the product distinct from that with the unmodified label, the modified product is a new product per section 910(a)(1)(A) of the FD&C Act
- How do you know if your label modification makes your product distinct and therefore a new tobacco product?
  - If the label has been modified and consumers are likely to perceive the product as "new" by virtue of the different label
- Examples of modifications that may render a product as "new":
  - Change in the product name
  - Addition of descriptors (e.g., premium tobacco)

SAME CHARACTERISTICS SE REPORT– SAME CHARACTERISTICS DEFINED

- What does it mean to have the same characteristics?
  - The new tobacco product has identical characteristics to the predicate tobacco product
- Same characteristics means there are no modifications to the materials, ingredients, design features, composition, heating source, or any other features of a tobacco product
- Examples of modifications that may fall under same characteristics:
  - Change in brand name to reflect the tobacco shop name
  - Change in background color from white to red
  - Change in identifiable pattern of colors and logo

SAME CHARACTERISTICS SE REPORT– MANUFACTURER OF NEW AND PREDICATE TOBACCO PRODUCTS

- Does the manufacturer need to be the same for the new and predicate tobacco products?
  - FDA expects the manufacturer to generally be the same
  - If not, we need adequate assurances that the characteristics are the same between the new and predicate tobacco products
- If the manufacturer is different for the new and predicate tobacco products, FDA strongly encourages the applicant to request a meeting to discuss possible ways to provide adequate assurances that the characteristics remain the same
  - For additional information on meetings, please refer to the CTP guidance, “Meetings with Industry and Investigators on the Research and Development of Tobacco products”

SAME CHARACTERISTICS SE REPORT– CONTENT

- Cover letter that identifies submission as Same Characteristics SE Report
- Unique identification of the new tobacco product
- Unique identification of the predicate tobacco product
- Statement if intend to commercially market both new and predicate product or if only intend to market the new product
- Environmental Assessment
- Health information summary or health information statement
- Statement of action to comply with section 907 of the FD&C Act
- If previously submitted SE report for new product, the submission tracking number for that previous SE report

SAME CHARACTERISTICS SE REPORT– CONTENT

- Certification signed by responsible official who is authorized to act on behalf of the company
  - *"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."*

SAME CHARACTERISTICS SE REPORT– WHEN TO SUBMIT NEW VERSUS AMEND PENDING SE REPORT

- May submit a Same Characteristics SE Report at any time

- May amend a pending SE Report to a Same Characteristics SE Report if the following is met:
  1. It is a provisional SE Report, and
  2. The new product as compared to the predicate product is eligible for a same characteristics SE Report* (i.e., the characteristics are identical), and
  3. The product subject to the provisional SE Report has not received an order or the report has not been withdrawn.

* In general the manufacturer will likely be the same for the new and predicate products. If different, FDA strongly encourages a meeting to discuss how to provide assurances that the characteristics are the same

SAME CHARACTERISTICS SE REPORT– MODIFICATIONS TO PROVISIONAL PRODUCTS THAT CREATE A DISTINCT PRODUCT

- If you modify the label of a provisional product and that modification to the label makes the product distinct, a premarket submission is required.
  - You may not amend your provisional report for this modification.
- 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:
  - FDA receives a Same Characteristics SE Report
    - Provide information on the provisional product and identify the STN assigned by FDA for the provisional SE Report
  - Do not commercially market the product until 90 days after FDA's receipt of the complete Same Characteristics SE Report
- If, based on the information received, FDA believes this is not appropriate for a Same Characteristics SE Report, it intends to notify the applicant.

SAME CHARACTERISTICS SE REPORT– MODIFICATIONS TO PROVISIONAL PRODUCTS THAT CREATE A DISTINCT PRODUCT

- What if you have already modified the label of a provisional product in a way that makes the product distinct, and are currently marketing this modified product?
  - For products already on the market as of the date of this guidance, FDA does not intend to object to the commercial distribution prior to FDA's issuance of an order under section 910(a) of the FD&C Act in the following situation:
    - FDA receives a Same Characteristics SE Report within 30 calendar days of the issuance of the guidance (i.e., received by CTP by April 3, 2015)
      - Provide information on the provisional product and identify the STN assigned by FDA for the provisional SE Report
  - If, based on the information received, FDA believes this is not appropriate for a Same Characteristics SE Report, it intends to notify the manufacturer.
- FDA intends to issue its order on the new product only after it has completed its review on the original provisional SE Report

PRODUCT QUANTITY CHANGE SE REPORT

PRODUCT QUANTITY CHANGE SE REPORT

- If the product quantity within a package has been modified, this is a new product per section 910(a)(1) of the FD&C Act as the characteristics have changed
- Examples of modifications that are new products:
  - Cigarette: Change from 20 per soft pack to 25 per soft pack
  - Roll-your-own: Change from 250 filtered cigarette tubes per box to 200 filtered cigarette tubes per box
  - Smokeless: Change in loose moist snuff from 2.0 oz per puck to 1.2 oz per puck

PRODUCT QUANTITY CHANGE SE REPORT– PRODUCT QUANTITY DEFINED

- What does it mean to only have a change in product quantity?
  - The only difference between the new tobacco product and the predicate product is a change in the quantity of the product
- A change in product quantity means there are no modifications to any other characteristics including per weight composition, design, heating source, or other features of a tobacco product (i.e., these are otherwise identical to the predicate tobacco product)
- Examples of modifications that are not a product quantity change:
  - Change in portion size of snus from 1.0 grams to 0.5 grams
  - Change in length of filtered cigarette tube from 79 mm to 98 mm
  - Change in diameter of cigarette

PRODUCT QUANTITY CHANGE SE REPORT– MANUFACTURER OF NEW AND PREDICATE TOBACCO PRODUCTS

- Does the manufacturer need to be the same for the new and predicate tobacco products?
  - FDA expects the manufacturer to generally be the same
  - If not, we need adequate assurances that the characteristics are the same between the new and predicate tobacco products with the exception of the product quantity
- If the manufacturer is different for the new and predicate tobacco products, FDA strongly encourages the applicant to request a meeting to discuss possible ways to provide adequate assurances that the characteristics remain the same
  - For additional information on meetings, please refer to the CTP guidance, “Meetings with Industry and Investigators on the Research and Development of Tobacco products”

PRODUCT QUANTITY CHANGE SE REPORT– CONTENT

- Cover letter that identifies submission as Product Quantity Change SE Report
- Unique identification of the new tobacco product
- Unique identification of the predicate tobacco product
- Statement if intend to commercially market both new and predicate product or if only intend to market the new product
- Environmental Assessment
- Health information summary or health information statement
- Statement of action to comply with section 907 of the FD&C Act
- If previously submitted SE report for new product, the submission tracking number for that previous SE report

PRODUCT QUANTITY CHANGE SE REPORT – CONTENT

- Certification signed by responsible official who is authorized to act on behalf of the company
  - *"I, [insert name of responsible official], on behalf of [insert name of company], certify that [insert new tobacco product name] is packaged in a different quantity from [insert name of predicate tobacco product] but is otherwise identical to [insert name of predicate tobacco product]. I certify that [insert name of company] understands this means there is 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."*

PRODUCT QUANTITY CHANGE SE REPORT – CONTENT

- Scientific data demonstrating that the change in product quantity is not likely to alter consumer behavior
- Examples of scientific data that may demonstrate the difference in characteristics which would not cause the new product to raise a different question of public health:
  - Studies showing that products of lower quantity are not more likely to be purchased as impulse purchases
  - 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
  - Peer-reviewed publications supporting that this specific change in product quantity does not substantially alter consumer behavior

PRODUCT QUANTITY CHANGE SE REPORT – WHEN TO SUBMIT NEW VERSUS AMEND PENDING SE REPORT

- May submit a Product Quantity Change SE Report at any time

- May amend a pending SE Report to a Product Quantity Change SE Report if the following is met:
  1. It is a provisional SE Report, and
  2. The new product as compared to the predicate product is eligible for a product quantity change SE Report* (i.e., the per weight composition, design, heating source, and other features are identical, and it is solely a product quantity change), and
  3. The product subject to the provisional SE Report has not received an order or the report has not been withdrawn.

* In general the manufacturer will likely be the same for the new and predicate products. If different, FDA strongly encourages a meeting to discuss how to provide assurances that the characteristics are the same

PRODUCT QUANTITY CHANGE SE REPORT – MODIFICATIONS TO PROVISIONAL PRODUCTS

- If you modify the product quantity of a provisional product, a premarket submission is required.
  - You may not amend your provisional report for this modification.
- 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:
  - FDA receives a Product Quantity Change SE Report
    - Provide information on the provisional product and identify the STN assigned by FDA for the provisional SE Report
  - Do not commercially market the product until 90 days after FDA's receipt of the complete Product Quantity Change SE Report
- If, based on the information received, FDA believes this is not appropriate for a Product Quantity Change SE Report, it intends to notify the applicant.

PRODUCT QUANTITY CHANGE SE REPORT – MODIFICATIONS TO PROVISIONAL PRODUCTS THAT CREATE A DISTINCT PRODUCT

- What if you have already modified the product quantity of a provisional product, and are currently marketing this modified product?
  - For products already on the market as of the date of this guidance, FDA does not intend to object to the commercial distribution prior to FDA's issuance of an order under section 910(a) of the FD&C Act in the following situation:
    - FDA receives a Product Quantity Change SE Report within 30 calendar days of the issuance of the guidance (i.e., received by CTP by April 3, 2015)
      - Provide information on the provisional product and identify the STN assigned by FDA for the provisional SE Report
  - If, based on the information received, FDA believes this is not appropriate for a Product Quantity Change SE Report, it intends to notify the manufacturer.
- FDA intends to issue its order on the new product only after it has completed its review on the original provisional SE Report

COMPARISONS BETWEEN TYPES OF SE REPORTS

TYPES OF SE REPORTS

- There are three types of SE Reports that may be submitted:
  - Same Characteristics SE Report
    - Where the characteristics between the new and predicate tobacco products are identical
  - Product Quantity Change SE Report
    - Where the product quantity has changed, but all other product characteristics, including per weight composition, design, heating source, and any other features are otherwise identical to the predicate tobacco product
  - Full SE Report
    - The “traditional” SE Report

SIMILARITIES OF THREE TYPES OF SE REPORTS

- Contains cover letter identifying submission
- Contains unique identification of new tobacco product
- Contains unique identification of predicate tobacco product
- Final order finding a product SE will not be issued without an eligible predicate product
- Contains health information summary or health information statement
- Contains statement of action to comply with section 907 of the FD&C Act
- Contains environmental assessment
- Contains previous STNs (if applicable)

DIFFERENCES BETWEEN THREE TYPES OF SE REPORTS

Same Characteristics SE Report	Product Quantity Change SE Report	Full SE Report
Will likely be same manufacturer for new and predicate products	Will likely be same manufacturer for new and predicate products	May be same or different manufacturers
Certification statement regarding product characteristics	Certification statement regarding product characteristics	No certification regarding product characteristics
All characteristics are identical	Only single modification – change in product quantity	Single or multiple modifications
No scientific data	Data demonstrating change in quantity does not cause the new product to raise different questions of public health. (In this case data demonstrating it is not likely to alter consumer use/behavior.)	Data on all characteristics and data demonstrating that the difference(s) in characteristics do not cause the new product to raise different questions of public health

QUESTIONS REGARDING TYPES OF SE REPORTS

Q: If I want to submit a Same Characteristics SE Report or Product Quantity Change SE Report but use a predicate that I do not manufacture, will the new product be found SE?

A: 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, you should contact FDA about possible ways to provide adequate assurances that the characteristics remain the same.

Q: I want to make both a product quantity change and a name change for my product. Can I submit both through a product quantity change SE Report?

A: 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 would like to make 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.

QUESTIONS REGARDING TYPES OF SE REPORTS

Q: What should I do if I changed the product name of my provisional product through an amendment three years ago, and am continuing to market this product with the new name in addition to the original provisional product?

A: For products already on the market as of the date of the guidance's issuance, that is March 4, 2015, 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) if FDA receives a Same Characteristics SE Report within 30 calendar days of the issuance of the guidance (i.e., received by CTP by April 3, 2015) and you provide information on the provisional product being modified and the STN assigned by FDA for the provisional SE Report.

QUESTIONS REGARDING TYPES OF SE REPORTS

Q: When will FDA issue a decision on a same characteristics or a product quantity change SE Report?

A: FDA intends to follow the performance goals for regular SE Reports which were implemented on October 1, 2014. However, for those cases where a same characteristics or product quantity change report is submitted and a provisional product is used as the predicate, the order will issue only after review of the provisional report is complete to ensure the predicate is eligible.

QUESTIONS REGARDING TYPES OF SE REPORTS

Q: I believe I have other modifications that only require a brief, specific set of information to be found substantially equivalent. Are there other types of SE Reports that I can utilize?

A: No. Currently the three types of SE Reports are a same characteristics SE Report, a product quantity change SE Report, and a full SE Report. If the modification does not fit the eligibility for a same characteristics SE Report or a product quantity change SE Report, you should submit a full SE Report.