Technical Project Lead (TPL) Review: SE0002648

SE0002648: North	
Package Type	Not provided
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
Common Attributes of SE Reports	
Applicant	Pacific Stanford Manufacturing Company
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Not provided
Recommendation	
Issue a Not Substantially Equivalent (NSE) Order.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.09.03 07:42:41 -04'00'

Matthew R. Holman, Ph.D.
Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by David Ashley -S
Date: 2015.09.03 07:44:00 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002648	North
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided

The product category, subcategory, and manufacturer are unknown for the predicate tobacco product.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the SE Report on December 10, 2010. FDA sent the applicant an Acknowledgement letter on November 16, 2011. FDA attempted on several occasions to identify additional information concerning the SE Report, including a fax on November 14, 2012 and an e-mail on December 4, 2012. On December 4, 2012, the applicant noted in an e-mail to FDA that, "Pacific Stanford no longer manufactures any cigarettes for sale locally or for export to the United States or elsewhere[1]. It closed its operations over two years ago." FDA informed the applicant that it will need to submit a formal withdrawal request if it would like to withdraw its SE Report. On January 4, 2013, FDA sent an Advice/Information Request letter to the applicant. On September 6, 2013, an e-mail was sent to inform the applicant that FDA still has not received an official withdrawal request. The applicant did not respond to FDA's e-mail. On August 11, 2014, FDA sent the applicant a Notification letter, informing the applicant that FDA expected to begin scientific review of its SE Report on September 25, 2014, and that FDA will review all amendments to the SE Report received no later than September 24, 2014. No amendments were received. On April 1, 2015, FDA issued the applicant a Preliminary Finding letter, instructing the applicant that a response was due by May 1, 2015. Because the applicant did not respond to the Preliminary Finding letter within thirty days of its issuance, on May 8, 2015, FDA called the applicant to ensure receipt of the Preliminary Finding Letter. FDA was unsuccessful in contacting the applicant on this attempt. On May 19, FDA called the applicant again. During this call, the applicant stated it had not received the Preliminary Finding letter and that the company has been closed for four years. To date, the applicant has not responded to the Preliminary Finding letter.

[1] See memorandum dated December 4, 2012.

1.3. SCOPE OF REVIEW

This review captures all administrative, compliance, and scientific reviews completed for this SE Report.

2. ADMINISTRATIVE REVIEW

An administrative completeness review was completed by Sarah Lee, MPH on January 4, 2013.

The completeness review concluded that the SE Report is *not* administratively complete because the SE Report was missing the following information:

- New tobacco products not uniquely identified
- Predicate tobacco products not uniquely identified
- No statement of basis for applicant's claims of substantial equivalence
- No health information summary or statement that such information would be provided upon request
- No side-by-side quantitative comparison new and predicate tobacco products with respect to "other features" (or statement that this is not applicable)
- No side-by-side quantitative comparison new and predicate tobacco products with respect to heating source (or statement that this is not applicable)
- No statement of compliance with standards under section 907 of the FD&C Act
- No environmental assessment

It should also be noted that deficiencies regarding "other features" and the heating source that were not included in the April 1, 2015, Preliminary Finding letter but should be included in the final order. As scientific review had not begun for this SE Report, it is important to include all deficiencies that were delayed until the start of substantive scientific review so the NSE order reflects all deficiencies for the application.

A regulatory review was completed by Aden Asefa on April 1, 2015. This review recommended issuance of a Preliminary Finding letter due to multiple deficiencies within the reports. The review noted that deficiencies regarding "other features" and the heating source were not to be included in the Preliminary Finding as these items would be addressed during scientific review. After issuance of the Preliminary Finding letter, the applicant did not respond. As the application is still deficient, it should be noted that FDA completed an environmental assessment, so the lack of an environmental assessment does not need to be conveyed to the applicant in the order letters. It should also be noted that deficiencies regarding "other features" and the heating source that were not included in the April 1, 2015, Preliminary Finding letter but should be included in the final orders. As scientific review had not begun for these SE Reports, it is important to include all deficiencies that were delayed until the start of substantive scientific review so the NSE order reflects all deficiencies for

the applications. The Preliminary Finding letter did not include a deficiency related to grandfathered status of the predicate tobacco product because the Office of Compliance and Enforcement (OCE) did not conduct a grandfather review due to lack of unique identification of the predicate tobacco product. However, the following deficiency should be included in the order letter so that the applicant is aware that this issue also prevented a determination of substantial equivalence:

1. Your SE Report lacks information to establish predicate eligibility (grandfathered status) for a tobacco product identified as the predicate product. The following information is needed to establish predicate eligibility:

    a. Evidence that demonstrates the predicate tobacco product was commercially marketed in the United States on February 15, 2007. Or, as alternative, evidence that the predicate tobacco product was commercially marketed, as close as possible to, both before and after February 15, 2007, could have been submitted. Examples of such evidence could have included, but not limited to, the following:

        - Dated copies of advertisements
        - Dated catalog pages
        - Dated promotional material
        - Dated trade publications
        - Dated bills of lading
        - Dated freight bills
        - Dated waybills
        - Dated invoices
        - Dated purchase orders
        - Dated customer receipts
        - Dated manufacturing documents
        - Dated distributor or retailer inventory lists
        - Any other document you believe demonstrates that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007

        If applicable, a brief statement explaining and identifying any citations or abbreviations (e.g., item number and/or product description) used in the evidence to reference the predicate tobacco products would be necessary.

    b. A statement that the predicate tobacco product was not exclusively in a test market as of February 15, 2007
    c. A complete description of the predicate tobacco product (as described above in Deficiency 2)
    d. A brief description of how the predicate tobacco product is used by the consumer

3. COMPLIANCE REVIEW

Compliance reviews were not completed because information to uniquely identify the predicate tobacco product was not provided in the SE Report.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Kimberly Agnew-Heard on February 17, 2015.

There is insufficient information to preliminarily determine the product characteristics of the new and predicate tobacco products and whether there are any differences in characteristics related to product chemistry. The following deficiencies were identified in the chemistry review:

1. Your SE Report lacks information to uniquely identify the new tobacco product. Multiple products for each new product could exist due to differences in package length, width, characterizing flavor, or additional descriptors. For unique identification, submit all of the following for each new product:

    a. Package quantity (e.g., 20 per pack)
    b. Product length (e.g., 89 mm, 100 mm)
    c. Product diameter (e.g., 6.7 mm, 8.1 mm)
    d. Characterizing flavor (e.g., none, tobacco, menthol)
    e. Additional descriptor (e.g., none, blue, single wide)

    In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement “Not Applicable.”

2. Your SE Report lacks information to uniquely identify the predicate tobacco product. Multiple products for each predicate product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, submit all of the following for each predicate product:

    a. Product name
    b. Product category
    c. Product subcategory
    d. Package quantity (e.g., 20 per pack)
    e. Product length (e.g., 89 mm, 100 mm)
    f. Product diameter (e.g., 6.7 mm, 8.1 mm)

g. Characterizing flavor (e.g., none, tobacco, menthol)
h. Additional descriptor (e.g., none, blue, single wide)

In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement “Not Applicable.”

3. Your SE Report does not include tobacco blend information other than tobacco leaf names and quantity in the new product. The limited information provided does not include sufficient detail to fully characterize the tobacco blend composition of the predicate and new products. We need any other information you may have that uniquely identifies the tobacco used in the predicate and new products. This is the information that you rely on to ensure that the tobacco used in the predicate and new products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the predicate and new products. Provide all of the following for the new and predicate products:

    a. All tobacco types used to manufacture the products
    b. Quantities of all tobacco types expressed in unit of measure, such as mass per cigarette
    c. Uniquely identify information for all tobacco (e.g., tobacco grading system)

    Tobacco blend changes between the new and predicate products may potentially affect the smoke chemistry, which have been shown to affect HPHC quantities. If there are any differences in tobacco blends between the new and predicate products, provide a rationale for each difference with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.

4. Your SE Report lists ingredients added to the tobacco with quantities for the new product. However, your SE Report does not include ingredients in all components of the predicate and new products. The ingredient information provided does not include sufficient detail to fully characterize the composition of the predicate and new products. Provide all of the following for the new and predicate products:

    a. All ingredients used to manufacture the products, include individual ingredients in complex ingredients
    b. Quantities of all ingredients expressed in unit of measure, such as mass per cigarette
    c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, function)

If there are any differences in composition between the new and predicate products, provide a rationale for each difference with evidence and a scientific rationale for why the difference does not cause the new product to raise different questions of public health.

5. Your SE Report lacks HPHC data for the new and predicate products. HPHC data can provide useful evidence to demonstrate that the difference in product composition between the new and corresponding predicate products do not cause the new products to raise different questions of public health. Because it is unclear what, if any, differences exist between the new and corresponding predicate products, it is unclear what HPHC data would be useful. However, if there are differences in product characteristics likely to affect HPHC quantities, then provide applicable HPHC data. If other modifications to the product are likely to change the levels of other HPHCs, provide the actual measured mean values of mainstream smoke yields of these also with variance expressed as standard deviation for the new and predicate products. For smoke analysis, the measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. If you provide HPHC data, provide full test data including the followings for all testing performed:

    a. Quantitative test protocols and method used
    b. Testing laboratory and their accreditation(s)
    c. Length of time between date(s) of manufacture and date(s) of testing
    d. National/international standards used and any deviations(s) from those standards. If deviation(s) is not the same for methods used for the new and predicate products, provide scientific evidence demonstrating that the testing result for the new and predicate products are accurate and comparable
    e. Number of replicates
    f. Standard deviations
    g. Complete data sets
    h. A summary of the results for all testing performed
    i. Storage conditions prior to initiating testing

It should be noted that a March 27, 2015, TPL memorandum revised Deficiency 1 and 2 from the chemistry review to read as follows:

1. Your SE Report lacks information to uniquely identify the new tobacco product. Multiple products for each new product could exist due to differences in package length, width, characterizing flavor, or additional

descriptors. For unique identification, submit all of the following for each new product:

a. Product subcategory (e.g., filtered combusted, non-filtered combusted)
b. Package type (e.g., hard pack, soft pack, clam shell)
c. Package quantity (e.g., 20 per pack)
d. Product length (e.g., 89 mm, 100 mm)
e. Product diameter (e.g., 6.7 mm, 8.1 mm)
f. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
g. Characterizing flavor (e.g., none, tobacco, menthol)
h. Additional descriptor (e.g., none, blue, single wide)

In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement "Not Applicable."

2. Your SE Report lacks information to uniquely identify the predicate tobacco product. Multiple products for each predicate product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, submit all of the following for each predicate product:

a. Product name
b. Product category (e.g., cigarette, roll-your-own, smokeless)
c. Product subcategory (e.g., filtered combusted, non-filtered combusted)
d. Package type (e.g., hard pack, soft pack, clam shell)
b. Package quantity (e.g., 20 per pack)
c. Product length (e.g., 89 mm, 100 mm)
d. Product diameter (e.g., 6.7 mm, 8.1 mm)
e. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
f. Characterizing flavor (e.g., none, tobacco, menthol)
g. Additional descriptor (e.g., none, blue, single wide)

In your response, it is necessary to address each item above, if any of the items listed does not apply, provide the statement "Not Applicable."

The revised Deficiency 1 and 2 includes additional descriptors needed to uniquely identify the new and predicate tobacco products that were not captured in the chemistry review. All of the chemistry deficiencies should be conveyed to the applicant except Deficiency 1 and 2 should be conveyed as stated in the TPL memorandum; the Preliminary Finding letter included Deficiency 1 and 2 as stated in the TPL memorandum.

4.2. ENGINEERING

An engineering review was completed by Erdit Gremi on February 18, 2015.

There is insufficient information to preliminarily determine the product characteristics of the new and predicate products and whether there are any differences in product design characteristics. The following deficiencies were identified in the engineering review:

1. Your SE Report provides minimal information on the design parameters for the predicate and new products. However, your SE Reports do not include all of the design parameters necessary to fully characterize the predicate and new products. In order to adequately characterize the products, it is necessary to compare key design parameters. Provide the **target specifications and upper and lower range limits** for all the following cigarette design parameters for each predicate and new product:

    a. Cigarette length (mm);
    b. Cigarette circumference (mm);
    c. Cigarette draw resistance (mm H_2O);
    d. Tobacco filler mass (mg);
    e. Tobacco rod density (g/cm^3)
    f. Tobacco oven volatiles (OV) (%);
    g. Filter ventilation (%);
    h. Tipping paper length (mm);
    i. Cigarette paper base paper basis weight (g/m^2);
    j. Cigarette paper base paper porosity (CU);
    k. Cigarette paper band porosity (CU);
    l. Cigarette paper band width (mm);
    m. Cigarette paper band space (mm);
    n. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)];
    o. Filter length (mm); and
    p. Filter pressure drop (mm H_2O).

    For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., paper length should be reported in mm per rolling paper). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

    If a difference exists between the new and corresponding predicate products, provide a rationale for each difference in the target specification and range limits with evidence and a scientific discussion for why the

difference does not cause the new product to raise different questions of public health.

2. Your SE Report provides minimal information on the design parameter specifications but do not include any data confirming that specifications are met. Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for all the following cigarette design parameters for each predicate and new product:

    a. Puff count;
    b. Cigarette draw resistance (mm H_2O);
    c. Tobacco filler mass (mg);
    d. Tobacco oven volatiles (OV) (%);
    e. Filter ventilation (%);
    f. Cigarette paper base paper basis weight (g/m_2);
    g. Cigarette paper base paper porosity (CU);
    h. Cigarette paper band porosity (CU);
    i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]; and
    j. Filter pressure drop (mm H_2O).

    If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

    Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis must include a target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data.

    Additionally, for the design parameters listed above that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

3. Your SE Report does not provide any information regarding the heating source for the new and corresponding predicate products. A description of the heating source is necessary for product characterization as defined in section 910(a)(3)(B) of the Food, Drug, & Cosmetic Act. Provide a description of the heating source.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on November 19, 2013, based on a programmatic environmental assessment for agency determinations that products are not substantially equivalent. The programmatic environmental assessment was prepared by Hoshing Chang, Ph.D., dated November 14, 2013.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products are unknown because the SE Report is devoid of any information about the characteristics of the new and predicate tobacco products. Because the applicant has not provided this information, the new tobacco product is not substantially equivalent.

The applicant has not provided sufficient information to determine that the predicate tobacco product is a grandfathered product.

An NSE order letter should be issued for the new tobacco product in SE0002648 as identified on the cover page of this review. The NSE order letter should cite the following deficiencies:

1. Your SE Report lacks information to uniquely identify the **new tobacco product**. Multiple products for the new tobacco product could exist due to differences in package length, width, characterizing flavor, or additional descriptors. For unique identification of the new tobacco product, *all* of the following are needed:

    a. Product subcategory (e.g., filtered combusted, non-filtered combusted)
    b. Package type (e.g., hard pack, soft pack, clam shell)
    c. Package quantity (e.g., 20 per pack)
    d. Product length (e.g., 89 mm, 100 mm)
    e. Product diameter (e.g., 6.7 mm, 8.1 mm)
    f. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
    g. Characterizing flavor (e.g., none, tobacco, menthol)
    h. Additional descriptor (e.g., none, blue, single wide)

2. Your SE Report lacks information to uniquely identify the **predicate tobacco product**. Multiple products for the predicate tobacco product could exist due to differences in package length, width, characterizing flavor, or additional descriptors. For unique identification of the predicate tobacco product, *all* of the following are needed:

    a. Product name
    b. Product category (e.g., cigarette, roll-your-own, smokeless)

c. Product subcategory (e.g., filtered combusted, non-filtered combusted)
d. Package type (e.g., hard pack, soft pack, clam shell)
e. Package quantity (e.g., 20 per pack)
f. Product length (e.g., 89 mm, 100 mm)
g. Product diameter (e.g., 6.7 mm, 8.1 mm)
h. Ventilation (e.g., none, 6.7 mm, 8.1 mm)
i. Characterizing flavor (e.g., none, tobacco, menthol)
j. Additional descriptor (e.g., none, blue, single wide)

3. Your SE Report does not include all of the design parameters necessary to fully characterize the predicate and new tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. The **target specifications and upper and lower range limits** for *all* the following cigarette design parameters for the predicate and new tobacco products were not provided:

   a. Cigarette length (mm)
   b. Cigarette circumference (mm)
   c. Cigarette draw resistance (mm H_2O)
   d. Tobacco filler mass (mg)
   e. Tobacco rod density (g/cm^3)
   f. Tobacco oven volatiles (OV) (%)
   g. Filter ventilation (%)
   h. Tipping paper length (mm)
   i. Cigarette paper base paper basis weight (g/m^2)
   j. Cigarette paper base paper porosity (CU)
   k. Cigarette paper band porosity (CU)
   l. Cigarette paper band width (mm)
   m. Cigarette paper band space (mm)
   n. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
   o. Filter length (mm)
   p. Filter pressure drop (mm H_2O)

   If a difference exists between the new and predicate tobacco products, a rationale for each difference in the target specification and range limits would be needed along with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report does not include any data confirming that specifications are met. *All* of the following **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance**

criteria, data sets, and a summary of the results are needed for the predicate and new tobacco products:

a. Puff count
b. Cigarette draw resistance (mm H_2O)
c. Tobacco filler mass (mg)
d. Tobacco oven volatiles (OV) (%)
e. Filter ventilation (%)
f. Cigarette paper base paper basis weight (g/m^2)
g. Cigarette paper base paper porosity (CU)
h. Cigarette paper band porosity (CU)
i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
j. Filter pressure drop (mm H_2O)

Certificates of analysis from the material supplier may satisfy this deficiency.

5. Your SE Report lacks any information regarding the heating source for the new and corresponding predicate products. A description of the heating source is necessary for product characterization as defined in section 910(a)(3)(B) of the FD&C Act.

6. Your SE Report lacks tobacco blend information other than tobacco leaf names and quantity in the new tobacco product. The limited information provided does not include sufficient detail to fully characterize the tobacco blend composition of the predicate and new tobacco products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the predicate and new products. *All* of the following items are needed for new and predicate tobacco products:

   a. All tobacco types used to manufacture the products
   b. Quantities of all tobacco types expressed in unit of measure, such as mass per cigarette
   c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

   If there are any differences in tobacco blends between the new and predicate tobacco products, evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

7. Your SE Report lists ingredients added to the tobacco with quantities for the new tobacco product. However, your SE Report does not include ingredients in all components of the predicate and new tobacco products. The ingredient information provided does not include sufficient detail to fully characterize the composition of the predicate and new tobacco products. *All* of the following would be needed to fully characterize the products:

    a. All ingredients used to manufacture the products, include individual ingredients in complex ingredients
    b. Quantities of all ingredients expressed in unit of measure, such as mass per cigarette
    c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, function)

    If any differences in composition between the new and predicate products, evidence and a scientific rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

8. Your SE Report lacks harmful and potentially harmful constituent (HPHC) data for the new and predicate tobacco products. HPHC data can provide useful evidence to demonstrate that the difference in product composition between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Because it is unclear what, if any, differences exist between the new and predicate tobacco products, it is unclear what HPHC data would be useful. However, if there are differences in product characteristics likely to affect HPHC quantities, then applicable HPHC data would be needed. For smoke analysis, the measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. *All* of the following information would be needed to evaluate the HPHC data:

    a. Quantitative test protocols and method used
    b. Testing laboratory and their accreditation(s)
    c. Length of time between date(s) of manufacture and date(s) of testing
    d. National/international standards used and any deviations(s) from those standards. If deviation(s) is not the same for methods used for the new and predicate products, provide scientific evidence demonstrating that the testing result for the new and predicate products are accurate and comparable
    e. Number of replicates
    f. Standard deviations
    g. Complete data sets

h. A summary of the results for all testing performed
i. Storage conditions prior to initiating testing

9. Your SE Report lacks the basis for your determination that new tobacco product is substantially equivalent to the predicate tobacco product. You did not provide the basis for your determination that the new tobacco product either (1) has the same characteristics as the predicate tobacco product (in accordance with 910(a)(3)(A)(i) of the FD&C Act), or (2) has different characteristics than the predicate tobacco product but the new tobacco product does not raise different questions of public health (in accordance with section 910(a)(3)(A)(ii) of the FD&C Act). As a reminder, characteristics, as used in the definition of substantial equivalence, is defined at section 910(a)(3)(B) of the FD&C Act as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

10. Your SE Report lacks an adequate summary of any health information related to your new tobacco product or a statement that such information will be made available upon request (section 910(a)(4) of the FD&C Act). Note that this requirement is separate from the requirement of section 904(a)(4) of the FD&C Act to submit certain health documents. You did not provide either an adequate summary of any health information or a statement that such information will be made available upon request.

11. Your SE Report lacks a statement of your action to comply with any standards under section 907 of the FD&C Act (see section 905(j)(1)(B) of the FD&C Act), including those standards under section 907(a) of the FD&C Act and any promulgated through regulation. For example, you did not provide a statement that the new tobacco product complies with the artificial or natural flavor ban in section 907(a)(1)(A).

12. Your SE Report lacks information to establish predicate eligibility (grandfathered status) for a tobacco product identified as the predicate product. The following information is needed to establish predicate eligibility:

    a. Evidence that demonstrates the predicate tobacco product was commercially marketed in the United States on February 15, 2007. Or, as alternative, evidence that the predicate tobacco product was commercially marketed, as close as possible to, both before and after February 15, 2007, could have been submitted. Examples of such evidence could have included, but not limited to, the following:

        - Dated copies of advertisements
        - Dated catalog pages
        - Dated promotional material

- Dated trade publications
- Dated bills of lading
- Dated freight bills
- Dated waybills
- Dated invoices
- Dated purchase orders
- Dated customer receipts
- Dated manufacturing documents
- Dated distributor or retailer inventory lists
- Any other document you believe demonstrates that the tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007

If applicable, a brief statement explaining and identifying any citations or abbreviations (e.g., item number and/or product description) used in the evidence to reference the predicate tobacco products would be necessary.

b. A statement that the predicate tobacco product was not exclusively in a test market as of February 15, 2007
c. A complete description of the predicate tobacco product (as described above in Deficiency 2)
d. A brief description of how the predicate tobacco product is used by the consumer