Technical Project Lead (TPL) Review: SE0000925, SE0010225-SE0010233

SE0000925: New Red King Size Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010225: New Blue King Size Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010226: New Light Blue King Size Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010227: New Dark Green King Size Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010228: New Light Green King Size Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided

SE0010229: New Red 100's Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010230: New Blue 100's Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010231: New Light Blue 100's Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010232: New Dark Green 100's Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
SE0010233: New Light Green 100's Box	
Package Type	Box
Package Quantity	Not provided
Length	Not provided
Diameter	Not provided
Filter Ventilation	Not provided
Characterizing Flavor	Not provided
Common Attributes of SE Reports	
Applicant	LIT Distributors, Inc.
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Not provided
Recommendation	
Issue Not Substantially Equivalent (NSE) Orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.10.02 10:06:22 -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: 2015.10.02 10:27:17 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0000925: **New Red King Size Box**	
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
SE0010225: **New Blue King Size Box**	
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
SE0010226: **New Light Blue King Size Box**	
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
SE0010227: **New Dark Green King Size Box**	
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

SE0010228: **New Light Green King Size Box**	
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
SE0010229: **New Red 100's Box**	
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
SE0010230: **New Blue 100's Box**	
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
SE0010231: **New Light Blue 100's Box**	
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
SE0010232: **New Dark Green 100's Box**	
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

SE0010233: **New Light Green 100's Box**	
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 category and subcategory where not provided for the predicate tobacco products. It is unclear who manufactures the predicate tobacco products.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted a single SE Report identifying the new tobacco product as New Brand Cigarettes on March 17, 2011. On April 4, 2013, the applicant submitted a correspondence clarifying that the "New" brand has several styles and the name of their products have designated colors in the names instead of light/low/mild type descriptors. Additionally, this correspondence requested grandfathered status for the various brand styles. An Acknowledgement letter issued on May 2, 2013, for SE0000925, the New Brand Cigarettes product. On September 10, 2013, the applicant submitted correspondence clarifying the new tobacco products for which they were seeking a substantial equivalence determination. It is unclear what prompted this correspondence.

After FDA review of the applicant's April 4, 2013, and September 10, 2013, correspondence, FDA identified discrepancies and attempted to contact the applicant for clarification. After several attempts to contact the applicant via telephone[1], FDA was able to reach the applicant on January 29, 2014. During that phone conversation, FDA provided the applicant with documentation (via email) regarding product submissions for SE review and for grandfathered status on, and requested that the applicant do the following:

1. Review the spreadsheet and verify the product names
2. Confirm correct corresponding predicate tobacco products
3. Provide package size for new and predicate tobacco products
4. Verify the names of those tobacco products for which a grandfathered request was submitted
5. Provide a change of address notification[2]
6. Provide all responses as official correspondence through the FDA Document Control Center in writing

[1] See the January 29, 2014, memo: On December 3, 2014, a voicemail was left for the applicant requesting that the company contact FDA. On December 5, 2014, FDA again attempted to contact the applicant by phone.
[2] A call occurred on November 3, 2014, during which the applicant confirmed that its address needed to be updated.

The applicant agreed to provide responses within two weeks (i.e., by February 12, 2014). To date, the applicant has not responded to this request.

On March 21, 2014, FDA created additional SE Reports (SE0010225-SE0010233) for the new tobacco products identified in the documentation provided to the applicant on January 29, 2014, and issued Acknowledgement letters[3]. On March 23, 2014, FDA issued a correction letter to SE0000925 to reflect the updated name of the new tobacco product as identified in the April 4, 2013, and September 10, 2013, correspondence from the applicant. On May 3, 2013, FDA conducted a Public Health Impact (PHI) review for SE0000925. An Advice/Information Request letter (A/I letter) was issued on May 10, 2013, for SE0000925 to request that the applicant provide information to determine whether the PHI Tier 1 assignment was accurate; the requested information included the identification of predicate tobacco products. The A/I letter was not returned, and the applicant did not respond to FDA's A/I request. On February 28, 2014, FDA conducted PHI reviews for SE0010225-SE0010233 and assigned them to PHI Tier 1.

On September 11, 2014, FDA issued a Notification letter for all of the SE Reports, indicating that scientific review was expected to begin on October 26, 2014, and that FDA would review all amendments received no later than October 25, 2014. FDA did not receive any amendments in response to the Notification letter. Because the new and predicate tobacco products are not uniquely identified, a Preliminary Finding letter was issued on April 1, 2015, with a response from the applicant due by May 1, 2015. On May 8, 2015, FDA called the applicant to confirm receipt of the Preliminary Finding letter, and the applicant indicated they may have the letters but needed to check. In case the applicant did not have the letter, FDA provided a courtesy copy of the Preliminary Finding letter after the phone call.

To date, FDA has not received any amendments in response to the A/I, Preliminary Finding, or Notification letters, nor has FDA received a request to withdraw the SE Reports. As a result, the Office of Science has been unable to request grandfathered review from the Office of Compliance and Enforcement or start substantive scientific review due to lack of basic information identifying the new and predicate tobacco products.

[3] With the issuance of the March 21, 2014 Acknowledgement letters, FDA applied the administrative record for SE0000925 (from receipt through March 21, 2014) to SE0010225-SE0010233.

Product Name	SE Report	Amendments
New Red King Size Box	SE0000925	SE0008407
New Blue King Size Box	SE0010225	
New Light Blue King Size Box	SE0010226	
New Dark Green King Size Box	SE0010227	
New Light Green King Size Box	SE0010228	
New Red 100's Box	SE0010229	
New Blue 100's Box	SE0010230	
New Light Blue 100's Box	SE0010231	
New Dark Green 100's Box	SE0010232	
New Light Green 100's Box	SE0010233	

1.3. SCOPE OF REVIEW

This review captures all administrative, compliance, and scientific reviews completed for these SE Reports.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Joanna Randazzo on March 17, 2014, for SE0010225-SE0010233 and on March 21, 2014, for SE0000925.

The final completeness reviews conclude that the SE Reports are *not* administratively complete because the following information is not included in the SE Reports:

- 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 of new and predicate tobacco products with respect to "other features" (or statement that this is not applicable)
- No side-by-side quantitative comparison of 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 assessments

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 letter as these items would be addressed during scientific review. The review recommended that the following deficiencies be included in the Preliminary Finding letter:

1. All of your SE Reports lack the basis for your determination that new tobacco products are substantially equivalent to predicate tobacco products. In all of your SE Reports, 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 section 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."

2. All of your SE Reports lack 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. Provide either an adequate summary of any health information or a statement that such information will be made available upon request.

   In future submissions, if the summary is included, it should contain detailed information regarding data concerning adverse health of the new tobacco product.

3. All of your SE Reports lack 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. Provide your statement to comply with the artificial or natural flavor ban in section 907(a)(1)(A).

To date, FDA has not received any amendments in response to any issued letters nor received any formal requests to withdraw the SE Reports.

It should be noted that the regulatory review concluded that there was inadequate information to proceed with substantive scientific review. However, OS did initiate substantive scientific review because the SE Report includes minimal information about the characteristics of the new and predicate tobacco products such that it was not possible to determine whether there are any differences in product characteristics between the new and predicate tobacco products. Conducting the scientific review resulted in the issuance of a Preliminary Finding letter that provides a more comprehensive list of missing information necessary to understand product characteristics and determine substantial equivalence of the new and predicate

tobacco product. The scientific review was limited to chemistry and engineering because these are the two disciplines that are responsible for ensuring that FDA has the basic characteristics related to product composition and design. Because the information in the SE Report is very limited, these reviews were completed shortly after the regulatory review was completed.

3. COMPLIANCE REVIEW

Compliance reviews were not completed because information to uniquely identify the predicate tobacco products was not provided in the SE Reports. Without information to uniquely identify a predicate tobacco product(s), FDA was unable to distinguish what tobacco product(s) the applicant was requesting a grandfathered determination for.

The Preliminary Finding letter should have included a deficiency requiring evidence to establish that the predicate tobacco product(s) was commercially marketed in the United States as of February 15, 2007. However, this deficiency was inadvertently omitted from the Preliminary Finding letter. Because the deficiency related to evidence to establish grandfathered status was not included in the Preliminary Finding letter, it cannot be a basis for an NSE determination. However, language should be included in an order letter regarding evidence to establish grandfathered status if the applicant chooses to submit these new and predicate tobacco products in a future SE Report(s).

Because the new tobacco products have not been determined to be substantially equivalent to the predicate tobacco products, OCE did not complete a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 910(a)(2)(A)(i)(II) of the FD&C Act.

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 Michael Morgan on February 18, 2015.

The chemistry review concludes that 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 composition. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All of your SE Reports for the **new tobacco products** lack information to uniquely identify the tobacco product. Multiple products for the new product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate products you are comparing to the new tobacco products are substantially equivalent. Your SE Reports only contains identification of the product name, category, subcategory, and package type for the new product. For unique identification, submit *all* of the following for each new product:

    a. Product subcategory
    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. Characterizing flavor (e.g., none, tobacco, menthol
    f. 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. All of your SE Reports for the **predicate tobacco products** lack information to uniquely identify the tobacco product. Multiple products for the predicate product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate products you are comparing to the new tobacco products are substantially equivalent. Your SE Reports contain information on the names of the new and predicate tobacco products, however it is not clear which tobacco products are the predicate products of each of the new tobacco products. For unique identification, submit *all* of the following each predicate product:

    a. Product name
    b. Product category
    c. Product subcategory
    d. Package type
    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. Characterizing flavor (e.g., none, tobacco, menthol
    i. 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. All of your SE Reports lack information about the tobacco blends and 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. All of your SE Reports lack ingredients added to tobacco in the predicate and new products. Furthermore, your SE Reports do not include ingredients in all components and subcomponents of the predicate and new products. Without this information, we cannot determine whether the predicate and new products are substantially equivalent. Similarly, for other ingredients, it would be helpful to know the grade of each ingredient. Provide a detailed list including:

    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 this information is identical for ingredients and additives in the predicate and new products, provide the information for the new product and a statement that this information is the same for its corresponding predicate product. 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. All of your SE Reports lack 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

Therefore, the applicant has failed to demonstrate that the differences in product characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

An engineering review was completed by Erdit Gremi on February 19, 2015.

The engineering review concludes that 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 design. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All your SE Reports provide 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* of 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., tipping paper length should be reported in mm per cigarette). 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. All your SE Reports provide 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* of 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. All your SE Reports do 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 for both the new and corresponding predicate products.

Therefore, the applicant has failed to demonstrate that the differences in product characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on November 19, 2013. The FONSI was supported by an environmental assessment prepared by FDA on November 14, 2013.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products are unknown because the SE Reports contain essentially no information about the characteristics of the new and predicate tobacco products. Therefore, the applicant has failed to provide sufficient information to support a finding of substantial equivalence.

The predicate tobacco products do not meet statutory requirements, as the applicant has not demonstrated that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

FDA examined the environmental effects of finding these new tobacco products not substantially equivalent and made a finding of no significant impact.

NSE order letters should be issued for the new tobacco products in SE0000925 and SE0010225-SE0010233, as identified on the cover page of this review. Additionally, the following text should be inserted **prior** to the list of deficiencies for all of the SE Reports:

> Your SE Report includes a predicate tobacco product which you indicate was commercially marketed in the United States as of February 15, 2007. As you did not provide information to uniquely identify the predicate tobacco product, a grandfathered determination could not be initiated. In future submissions, if you choose to use a predicate tobacco product that was commercially marketed in the United States as of February 15, 2007, but has not yet been determined to be grandfathered by FDA, evidence must be submitted to demonstrate commercial marketing in the United States as of February 15, 2007.

The NSE order letters for all of the SE Reports should cite the following deficiencies:

1. Your SE Report for the **new tobacco product** lacks information to uniquely identify the tobacco product. Multiple products for the new tobacco product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate tobacco product you are comparing to the new tobacco product is substantially equivalent. Your SE Report only contains identification of the product name, category, subcategory, and package type for the new tobacco product. For unique identification, *all* of the following information is needed:

    a. Product subcategory

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, 10%, 25%)
f. Characterizing flavor (e.g., none, tobacco, menthol)
g. Additional descriptor (e.g., none, blue, single wide)

2. Your SE Report for the **predicate tobacco product** lacks information to uniquely identify the tobacco product. Multiple products for the predicate tobacco product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate tobacco product you are comparing to the new tobacco product is substantially equivalent. Your SE Reports contain information on the names of the new and predicate tobacco products, however it is not clear which tobacco products are the predicate tobacco products of each of the new tobacco products. For unique identification, *all* of the following information is needed:

    a. Product name
    b. Product category
    c. Product subcategory
    d. Package type
    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, 10%, 25%)
    i. Characterizing flavor (e.g., none, tobacco, menthol)
    j. Additional descriptor (e.g., none, blue, single wide)

3. Your SE Report lacks information about the tobacco blends and sufficient detail to fully characterize the tobacco blend composition of the predicate and new tobacco products. We need any other information you may have that uniquely identifies the tobacco used in 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 tobacco products. *All* of the following information about the tobacco blends is needed for the 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. Uniquely identify information for all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco 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 tobacco products, a rationale for each difference with 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.

4. Your SE Report lacks ingredients added to tobacco in the predicate and new tobacco products. Furthermore, your SE Reports do not include ingredients in all components and subcomponents of the predicate and new tobacco products. Without this information, we cannot determine whether the predicate and new products are substantially equivalent. A detailed list of ingredient information including *all* of the following information is needed for the new and predicate tobacco 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 tobacco products, a rationale for each difference with 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.

5. Your SE Report lacks 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 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 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 applicable HPHC data would be needed. For smoke analysis, the measurement of HPHC yields under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. Full test data including the followings would be needed 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

6. 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. **Target specifications and upper and lower range limits** are needed for *all* of the following design parameters for the predicate and new tobacco products:

   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)

   For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). 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.

7. Your SE Report does not include any data confirming that specifications are met. **Test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** is needed for *all* of the following design parameters 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. The certificates of analysis would need to 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.

8. Your SE Report does not provide any information regarding the heating source for the new and predicate tobacco 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.

9. Your SE Report lacks the basis for your determination that the new tobacco product is substantially equivalent to a predicate tobacco product. The basis for your determination is that the new tobacco product either (1) has the same characteristics as the predicate tobacco product (in accordance with section 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. In future submissions, if a health information summary is included, it should contain detailed information regarding data concerning adverse health of the new tobacco product.

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.