Technical Project Lead (TPL) Review: SE0002138-SE0002148

SE0002138: Predator Straight	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002139: Predator Wintergreen	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Wintergreen[1]
SE0002140: Predator Mint	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Mint[1]
SE0002141: Revved Up Straight	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002142: Revved Up Mint	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Mint[1]
SE0002143: Dukes Original	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002144: Dukes .50 Caliber	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided

[1]FDA determined characterizing flavor based on the tobacco product name. The applicant did not provide characterizing flavor or state that there was no characterizing flavor. In addition, the SE Report lacked data to evaluate whether the flavor was characterizing.

SE0002145: Warrior Straight	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002146: Warrior Wintergreen	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Wintergreen[1]
SE0002147: Warrior Mint	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Mint[1]
SE0002148: Revved Up Wintergreen	
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Wintergreen[1]
Common Attributes of SE Reports	
Applicant	Southern Tobacco Company
Report Type	Provisional
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Not Substantially Equivalent (NSE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2016.02.09 12:06:03 -05'00'

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: 2016.02.09 13:25:07 -05'00'

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:

SE0002138: Predator Straight	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002139: Predator Wintergreen	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002140: Predator Mint	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002141: Revved Up Straight	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002142: Revved Up Mint	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002143: Dukes Original	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided

SE0002144: Dukes .50 Caliber	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002145: Warrior Straight	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002146: Warrior Wintergreen	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002147: Warrior Mint	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided
SE0002148: Revved Up Wintergreen	
Product Name	Not provided
Package Type	Not provided
Package Quantity	Not provided
Tobacco Particle Size	Not provided
Characterizing Flavor	Not provided

Specific predicate tobacco products have not been identified by the applicant for any of the SE Reports. Therefore, it is unclear who manufactures the predicate tobacco products.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

These 11 SE Reports were submitted on March 20, 2011. FDA issued Acknowledgement letters for these SE Reports on November 3, 2011. For STNs SE0002139, SE0002141-SE0002143, and SE0002145-SE0002147, a regulatory review completed on October 10, 2012 concluded that the SE Reports were administratively incomplete. Therefore, on October 10, 2012, FDA issued an Advice/Information Request letter (A/I letter) to obtain the information needed in order for the SE Reports to be administratively complete. For STNs SE0002138, SE0002140, SE0002144, and SE0002148 a regulatory review completed on

October 26, 2012, concluded that the SE Reports were administratively incomplete. Therefore, on October 26, 2012, FDA issued an Advice/Information Request letter (A/I letter) to obtain the information needed in order for the SE Reports to be administratively complete. FDA spoke with the applicant on December 13, 2012, as follow-up to both A/I letters regarding all 11 SE Reports, and the applicant informed FDA that it is no longer selling the tobacco products contained in the SE Reports. During the call, FDA provided the applicant with three options for proceeding: (1) do not respond; FDA will continue to review the SE Reports; (2) respond to FDA's A/I letters by amending the SE Reports; FDA will continue to review its SE Reports; and (3) withdraw the SE Reports. [2] The applicant did not amend or withdraw the SE Reports (i.e., the applicant chose the first option).

On December 9, 2012, FDA conducted Public Health Impact (PHI) reviews of these SE Reports. FDA issued an A/I letter on May 10, 2013, 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 FDA spoke to the applicant on October 4, 2013, to ensure that the applicant was aware of the A/I letter.[3] Because the applicant did not respond to the May 10, 2013 A/I letter, the SE Reports remained classified as PHI Tier 1.

On July 11, 2014, FDA issued a Notification letter informing the applicant that scientific review of the SE Reports was expected to begin on August 25, 2014. The applicant did not amend or withdraw the SE Reports. Therefore, FDA issued a Preliminary Finding letter for the SE Reports on October 3, 2014, to obtain information needed to uniquely identify each new and predicate tobacco product. The regulatory health project manager called the applicant on October 14 and November 5, 2014, to confirm that the Preliminary Finding letter was received. The applicant did not answer the phone on either occasion; the regulatory health project manager left voicemails on both dates.[4] The applicant did not amend or withdraw the SE Reports in response to the Preliminary Finding letter.

It should be noted that the October 3, 2014 Regulatory Review concluded that there was inadequate information to support a finding of substantial equivalence. However, OS did initiate 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 another Preliminary Finding letter that provides a more comprehensive list of missing information necessary to determine substantial equivalence of the new and predicate tobacco product. The scientific review was limited to chemistry and

[2] Memorandum to the File, December 13, 2012.
[3] Memorandum to the File, October 4, 2013.
[4] Memorandum to the File, October 14, 2014; Memorandum to the File, November 5, 2014.

engineering because these are the two disciplines that are responsible for ensuring that FDA has the basic characteristics related to product composition and design. FDA issued the second Preliminary Finding letter on May 5, 2015 with a response due date of June 4, 2015. This Preliminary Finding letter was based on scientific reviews conducted by FDA. On May 8, 2015, FDA attempted to call the applicant to ensure that the applicant had received the Preliminary Finding letter; one of the two phone numbers provided by the applicant was no longer in service. FDA left a voicemail message on the working phone number because the applicant did not answer the phone.[5] On May 11, 2015, FDA contacted the applicant and confirmed from an employee who answered the call that the contact number belongs to the applicant.[6] Because the applicant did not contact FDA, on May 26, 2015, FDA e-mailed the applicant to follow-up on the Preliminary Finding letter. The applicant replied to FDA that the applicant no longer produces the new tobacco products and indicated that they have informed FDA of this on more than one occasion.[7]

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.

1.3. SCOPE OF REVIEW

This memo captures the administrative reviews completed for these SE Reports.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Dan Gonski on October 10 and 26, 2012.

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)

[5] Memorandum to the File, May 8, 2015.
[6] Memorandum to the File, May 11, 2015.
[7] Memorandum to the File, May 26, 2015.

- 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 October 3, 2014. 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 information to fully identify the new tobacco products. Submit all of the following for each new product:

    a. Product name (brand and sub-brand)
    b. Category (e.g., cigarette, smokeless tobacco, cigarette tobacco)
    c. Subcategory (e.g., loose, portioned)
    d. Package type (e.g., pouch, plastic, can, cardboard)
    e. Package size/weight per package/weight (e.g., 30 grams, 15 count)
    f. Flavor (e.g., licorice, menthol)
    g. Cut/style (if applicable) (e.g., long cut, fine cut)
    h. Additional descriptor (e.g., blue, green, gold)

    For example, you did not specify the product category, subcategory, package type, package size/weight, flavor, cut/style or any additional descriptors. As there could be multiple products due to differences in dimensions, count, package type, or additional descriptors (if applicable); use the list of product attributes above to specify the new product.

2. All of your SE Reports lack information to fully identify the predicate tobacco products. Submit all of the following for each predicate product:

    a. Product name (brand and sub-brand)
    b. Category (e.g., cigarette, smokeless tobacco, cigarette tobacco)
    c. Subcategory (e.g., loose, portioned)
    d. Package type (e.g., pouch, plastic, can, cardboard)
    e. Package size/weight (e.g., 30 grams)
    f. Flavor (e.g., licorice, menthol)
    g. Cut/style (if applicable) (e.g., long cut, fine cut)
    h. Additional descriptor (e.g., blue, green, gold)

    For example, you did not identify your predicate tobacco product(s) for the SE Reports listed above. In order to commence with the review, specify the

predicate tobacco products to which you are proposing to find your new tobacco products substantially equivalent. In addition, fully identify your predicate tobacco products as there could be multiple products associated with each of the items in the list above.

3. All of your SE Reports do not include the basis for your determination that your new tobacco product is substantially equivalent to a predicate tobacco product. State 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). 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."

4. All of your SE Reports lack an adequate summary of health information (section 910(a)(4)(B) of the FD&C Act) related to your new tobacco product or a statement that it will be made available upon request (section 910(a)(4)(A) of the FD&C Act). If the summary is included, it should contain detailed information on data of the concerning adverse health effects and information related to the new tobacco product, not be limited to results of studies on the new tobacco products. This requirement is separate from the requirement of section 904(a)(4) to submit certain health documents. Provide the summary or a statement that it will be made available upon request.

5. All of your SE Reports lack a statement of your action to comply with the requirements of 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. If any of the standards are not applicable to your new products, provide a statement to that effect. Submit your statement of action to comply with the requirements of section 907.

It should be noted that the product name, category, and subcategory for each new tobacco product was provided by the applicant. And, FDA determined the characterizing flavor for some of the new tobacco products based on the product name. Therefore, Deficiency 1 in this review are not consistent with Deficiency 1 in the chemistry review[8]. The deficiency in the chemistry review reflects the known product name, category, and subcategory of the new tobacco product. Therefore, Deficiency 1 in the chemistry review should be communicated to the applicant (rather than Deficiency 1 in the regulatory review). It is important to note that Deficiency 1 in the chemistry review includes characterizing flavor; characterizing flavor should be included for all SE Reports because the applicant did not state the characterizing flavor for any of the tobacco products. Deficiency 1 in the regulatory

[8] See section 4.1 of this review.

review captures tobacco cut size is a discrete type of information needed for unique identification, while Deficiency 1 in the chemistry review capture tobacco cut size as part of “additional descriptor.” Tobacco cut size should be captured as a discrete type of information, consistent with Deficiency 1 in the regulatory review.

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 Fuqiang Liu on March 5, 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 packaging. Multiple products for the

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

a. Package type
b. Package quantity (e.g., 30 grams, 50 grams)
c. Characterizing flavor (e.g., none, cherry, wintergreen)
d. Additional descriptor (e.g., none, long cut)

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 packaging. Multiple products for the predicate product could exist due to differences in package quantity, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate products you are comparing to the new tobacco products are substantially equivalent. For unique identification, submit all of the following:

a. Product name
b. Product category
c. Product subcategory
d. Package type
e. Package quantity (e.g., 20 per pack)
f. Characterizing flavor (e.g., none, tobacco, wintergreen)
g. Additional descriptor (e.g., none, long cut)

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 package
    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, all of your SE Reports lack 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 regarding the tobacco used in the predicate and new products. 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 package
    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 deviation(s)
    g. Complete data sets
    h. A summary of the results for all testing performed
    i. Storage conditions prior to initiating testing

6. All of your SE Reports lack information about stability for the predicate or new products. Additional information about stability testing would allow us to understand specifically how the stability is determined for the predicate and new products. Provide detailed stability testing, including test protocols, quantitative acceptance criteria, data sets and a summary of the results for all stability testing performed. Additionally, provide any known or expected impacts of the differences in characteristics on the product stability of the predicate and new products. If no impact is known or expected, state as such.

7. All of your SE Reports lack packaging information for the predicate and new products. In order to fully identify the predicate and new products, additional information about the packaging is needed. If the packaging materials are identical for both products, provide detailed material information, including a detailed ingredients list, for the wrap, foil and cardboard packaging of the new products. If any differences exist in any components or ingredients of the packaging (e.g., film, foil, tear tape, blanks, inks, board, adhesives), provide a side-by-side comparison of the packaging to identify each difference.

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 Aarthi Arab on March 3, 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 of your SE Reports lack information on 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 rolling paper design parameters for each predicate and new product:

    a. Tobacco particle size (mm);
    b. Final tobacco moisture (%);
    c. Portion length (mm) (if applicable);
    d. Portion width (mm) (if applicable);
    e. Portion mass (mg) (if applicable);
    f. Portion thickness (mm) (if applicable);
    g. Pouch paper porosity (CU) (if applicable); and
    h. Pouch paper basis weight (g/m^2) (if applicable).

    For each of the above parameters, provide the needed data on a per unit of product basis (e.g., portion mass should be reported in grams per portion). If a design parameter is not applicable (e.g., pouch paper porosity if the tobacco is not portioned into pouches), state as such and provide a scientific rationale.

Since you have stated that you do not manufacture your potential predicate products, provide an explanation and certify that you have access to the product design information for the predicate product (from its manufacturer). Alternatively, if you manufacture the predicate product, state as such.

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 of your SE Reports lack design parameter specifications and 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 rolling paper design parameters for each predicate and new product:

    a. Tobacco particle size (mm);
    b. Final tobacco moisture (%);
    c. Portion mass (mg) (if applicable);
    d. Pouch paper porosity (CU) (if applicable); and
    e. Pouch paper basis weight (g/m^2) (if applicable).

    For each of the above parameters, provide the needed data on a per unit of product basis (e.g., portion mass should be reported in grams per portion). If a design parameter is not applicable (e.g., pouch paper porosity if the tobacco is not portioned into pouches), 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.

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 Hoshing Chang, Ph.D., 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 SE0002138-SE0002148, 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, and subcategory for the new tobacco product. For unique identification, *all* of the following information is needed:

a. Package type (e.g., plastic can, cardboard can with plastic lid)
b. Package quantity (e.g., 30 grams, 50 grams)
c. Characterizing flavor (e.g., none, cherry, menthol)
d. Tobacco cut size (e.g., 0.5 mm, 3 mm)
e. Additional descriptor (e.g., blue, green, gold)

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. Category (e.g., cigarette, smokeless tobacco, cigarette tobacco)
c. Subcategory (e.g., loose, portioned)
d. Package type (e.g., plastic can, cardboard can with plastic lid)
e. Package quantity (e.g., 30 grams, 50 grams)
f. Characterizing flavor (e.g., none, cherry, menthol)
g. Tobacco cut size (e.g., 0.5 mm, 3 mm)
h. Additional descriptor (e.g., blue, green, gold)

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. Information to uniquely identify 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 lacks information about stability of the new and predicate tobacco products. Detailed stability testing, including test protocols, quantitative acceptance criteria, data sets and a summary of the results for all stability testing performed is needed to understand the stability of the new and predicate tobacco products. If there are differences in stability, scientific rationale and evidence would be needed to demonstrate that the differences do not cause the new tobacco product to raise different questions of public health.

7. Your SE Report lacks packaging information for the new and predicate tobacco products. In order to fully identify the predicate and new products, additional information about the packaging is needed. If there are differences in packaging, scientific rationale and evidence would be needed to demonstrate that the differences do not cause the new tobacco product to raise different questions of public health.

8. 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 new and predicate tobacco products:

    a. Tobacco particle size (mm)
    b. Moisture (%)
    c. Portion length (mm) (if applicable)
    d. Portion width (mm) (if applicable)
    e. Portion mass (mg) (if applicable)
    f. Portion thickness (mm) (if applicable)
    g. Pouch paper porosity (CU) (if applicable)
    h. Pouch paper basis weight (g/m^2) (if applicable)

    If there are differences in any of these parameters, a scientific rationale and evidence would be needed for each difference to demonstrate that the

differences do not cause the new tobacco product to raise different questions of public health.

9. 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 new and predicate tobacco products:

    a. Tobacco particle size (mm)
    b. Moisture (%)
    c. Portion mass (mg) (if applicable)
    d. Pouch paper porosity (CU) (if applicable)
    e. Pouch paper basis weight (g/m^2) (if applicable)

    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.

10. 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.”

11. 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.

12. 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.