Technical Project Lead (TPL) Review: SE0001079 and SE0003613 – SE0003621

SE0001079: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	84 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003613: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	100 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003614: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	84 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003615: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	100 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003616: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	84 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided

SE0003617: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	100 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003618: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	84 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003619: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	100 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003620: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	84 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
SE0003621: North	
Package Type	Hard Box
Package Quantity	Not Provided
Length	100 mm
Diameter	Not Provided
Filter Ventilation	Not Provided
Characterizing Flavor	Not Provided
Common Attributes of SE Reports	
Applicant	Eagle River Importers, Inc.
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Not Substantially Equivalent (NSE) Orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.05.19 06:34:04 -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: 2015.05.19 06:56:39 -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 predicate tobacco product is a RYO tobacco filler product imported from Pacific Stanford (Philippines). The applicant did not submit any other information for any of the predicate tobacco products:

Product Name	North RYO Blend 2005
Package Type	Not Provided
Package Quantity	Not Provided
Characterizing Flavor	Not Provided

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted these 10 SE Reports on March 20, 2011. Acknowledgement letters were issued on September 16, 2011. On September 19, 2011, and September 23, 2011, FDA conducted jurisdiction reviews for SE0001079 and SE0003613-SE0003621, respectively. On August 15, 2012, and August 21, 2012, FDA conducted Public Health Impact (PHI) reviews for SE0001079 and SE0003613-SE0003621, respectively. The SE Reports were found administratively incomplete after conducting completeness reviews on May 6, 2013; additionally, an administrative advice/information (A/I) request letter was issued on May 6, 2013. FDA issued a Public Health Impact (PHI) Advice/Information (A/I) request letter for these SE Reports on May 10, 2013. On June 28, 2013, the applicant requested a 30-day extension (SE0009154) to respond to the May 6, 2013, A/I letter; however, extensions were already in effect as stated in the May 10, 2013, A/I letter, which granted the applicant staggered dates to provide FDA with the requested information. No further response was received from the applicant regarding the two A/I letters. On October 10, 2014, FDA issued a notification letter for SE0001079 and SE0003613-SE0003621. This letter noted that scientific review was to begin on November 25, 2014, and that FDA would review all amendments received no later than November 24, 2014. FDA received no response to the notification letter. A Preliminary Finding letter was issued on February 6, 2015, with a response due date of March 8, 2015. In a follow-up phone call by the RHPM placed on February 12, 2015, to confirm receipt of the Preliminary Finding letter, the applicant expressed its intent to (b)(4) 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.

Product Name	SE Report	Amendment
North	SE0001079	SE0009154
North	SE0003613	
North	SE0003614	
North	SE0003615	
North	SE0003616	
North	SE0003617	
North	SE0003618	
North	SE0003619	
North	SE0003620	
North	SE0003621	

1.3. SCOPE OF REVIEW

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

2. ADMINISTRATIVE REVIEW

An administrative completeness review was completed by La'Shelle Tatum on May 6, 2013.

The completeness review concluded that the SE Reports are *not* administratively complete because the SE Reports were 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 assessments

A regulatory review was completed by Cecilia Robinson on February 5, 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. However in addition to administrative incompleteness, there was a lack of evidence to demonstrate the predicate product was commercially marketed in the United States as of

February 15, 2007. Therefore, the following deficiency was added to the Preliminary Finding letter:

1. All of your SE Reports lack 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 the unique identification deficiency)
    d. A brief description of how the predicate tobacco product is used by the consumer

If you have submitted this information in a stand-alone GF submission, you may satisfy this deficiency by providing the submission tracking number of the GF submission.

After issuance of the Preliminary Finding letter, the applicant did not submit any amendments or a formal request to withdraw the SE Reports. As the applications are still deficient, it should be noted that FDA completed an environmental assessment in 2013 for all NSE orders, so the lack of an environmental assessment does not need to be conveyed to the applicant in the order letters. It was included in the Preliminary Finding letter because FDA did not know at that time whether SE or NSE orders would be issued. It should also be noted that deficiencies regarding "other features" and the heating source that were not included in the February 6, 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.

3. COMPLIANCE REVIEW

Compliance reviews were not completed because information to uniquely identify the predicate tobacco product was not provided in the SE Reports. However, a deficiency related to evidence to establish grandfather status for the predicate was provided as part of regulatory review finalized on February 5, 2015.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science because the applicant did not provide information sufficient to uniquely identify the new and predicate tobacco products.

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 Reports are devoid of information about the characteristics of the new and predicate tobacco products, and, therefore, the applicant has failed to demonstrate that, the new tobacco products are substantially equivalent.

The applicant has not provided sufficient information to determine that the predicate tobacco products are grandfathered products.

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 SE0001079 and SE0003613 – SE0003621, as identified on the cover page of this review. The NSE order letters 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 quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, *all* of the following is needed:

    a. Package quantity (e.g., 20 cigarettes per pack)
    b. Product diameter (e.g., 6.7 mm, 8.1 mm)
    c. Filter ventilation (e.g., none, 10%, 25%)
    d. Characterizing flavor (e.g., none, tobacco, menthol)

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 quantity, length, width, characterizing flavor, or additional descriptors. For unique identification, *all* of the following is needed:

    a. Package type (e.g., soft pack, box)
    b. Package quantity (e.g., 20 cigarettes per pack)
    c. Characterizing flavor (e.g., none, tobacco, menthol)

3. 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.”

4. 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.

5. Your SE Report lacks a side-by-side quantitative comparison of the new and predicate tobacco products with respect to “other features” as identified in section 910(a)(3)(B) of the FD&C Act. For example, your SE Report does not include any HPHC data. And, your SE Report does not contain a statement that there are no applicable “other features.”

6. Your SE Report does not include side-by-side quantitative comparison of the new and predicate tobacco products with respect to heating sources

7. 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).

8. 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