Technical Project Lead (TPL) Review: SE0000098 - SE0000100

SE0000098: Longhorn Fine Cut Natural 34.02 g	
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0000099: Longhorn Long Cut Natural 34.02 g	
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0000100: Longhorn Long Cut Wintergreen 34.02 g	
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Wintergreen
Common Attributes of SE Reports	
Applicant	Swedish Match USA, Inc.
Report Type	Provisional
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] Cuts per inch (CPI)

Technical Project Lead (TPL):

Todd L. Cecil -S
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Date: 2017.09.25 08:26:56 -04'00'

Todd L. Cecil, Ph.D.
Chemistry Branch Chief
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 Matthew R. Holman -S
Date: 2017.09.25 10:03:56 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0000098: Longhorn Fine Cut Natural 34.02 g	
Product Name	Longhorn Fine Cut Natural 37.42 g
Package Type	Can
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0000099: Longhorn Long Cut Natural 34.02 g	
Product Name	Longhorn Long Cut Natural 37.42 g
Package Type	Can
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0000100: Longhorn Long Cut Wintergreen 34.02 g	
Product Name	Longhorn Long Cut Wintergreen 37.42 g
Package Type	Can
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Wintergreen

The predicate tobacco products are loose moist snuff smokeless tobacco products manufactured by Swedish Match USA, Inc.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

Swedish Match USA, Inc. submitted the above referenced Substantial Equivalence (SE) Reports on March 8, 2011, which were received by FDA on March 10, 2011. On July 19, 2011, FDA completed Jurisdiction Reviews and issued an Acknowledgement letters to the applicant. On July 5, 2012, FDA received an Environmental Assessment for the SE Reports listed above. FDA conducted a review of the SE Reports on December 27, 2012 and issued an Advice/Information Request (A/I) letter. On January 25, 2013, FDA received the applicant's response to the A/I letter and conducted a review on February 20, 2013. This review concluded the SE Reports were administratively complete. On August 11, 2015, FDA issued a Notification letter to notify the applicant of the date scientific review was expected to begin. On September 13, 2016, FDA issued an A/I letter to inform the applicant of deficiencies identified during scientific review. FDA received the applicant's response on November 9, 2016. On February 8, 2017, FDA issued a Preliminary Finding letter and a correction to

this letter on February 24, 2017. The applicant responded to the Preliminary Finding letter on March 10, 2017. On May 25, 2017, FDA issued another Preliminary Finding letter, which contained deficiencies solely from the environmental review for information FDA needed to complete its environmental assessment. Following issuance of this letter, the applicant submitted an extension request on May 30, 2017. On June 14, 2017, FDA issued an extension granted letter, extending the response due date for the Preliminary finding letter to July 24, 2017. The applicant's response to the Preliminary Finding letter was received by FDA on July 19, 2017. On July 31, 2017, FDA issued a rescission of the Preliminary Finding letter. As these SE Reports are provisional SE Reports, issuance of SE orders for each of these SE Reports falls within a class of actions that are ordinarily categorically excluded from environmental assessment under 21 CFR 25.35(a).[2] The applicant had provided the necessary information for a claim of categorical exclusion, including a statement of no extraordinary circumstances, prior to the issuance of the Preliminary Finding letter. Accordingly, since the deficiencies that had been included in the Preliminary Finding letter were limited to information needed for FDA to complete its environmental assessment, no deficiencies remained so the Preliminary Fining letter was rescinded.

Product Name	SE Report	Amendments
Longhorn Fine Cut Natural 34.02 g	SE0000098	SE0004654 SE0006488 SE0008261 SE0012385 SE0013740 SE0013982 SE0014126 SE0014204
Longhorn Long Cut Natural 34.02 g	SE0000099	SE0004654 SE0006489 SE0008261 SE0012385 SE0013740 SE0013982 SE0014126 SE0014204

[2] *See* National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions, 80 FR 57531 (Sept. 24, 2015).

Product Name	SE Report	Amendments
Longhorn Long Cut Wintergreen 34.02 g	SE0000100	SE0004654 SE0006490 SE0008261 SE0012385 SE0013740 SE0013982 SE0014015 SE0014126 SE0014204

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Stephanie Redus on December 27, 2012, Joanna Randazzo on February 20, 2013, Cecilia Robinson on November 14, 2016, and Shireen Ahmad on June 14, 2017, and July 28, 2017.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated September 15, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by John Gong on July 5, 2016, and by Mimy Young on December 29, 2016, and April 28, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco

products but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

The new tobacco products have the following key differences compared to the predicate tobacco products:

- Differences in package quantity: 9% decrease in weight from 37.42 grams to 34.02 grams in all of the SE Reports
- Differences in tobacco blend in SE0000098 and SE0000099[3]
- Change in HPHC yields ranging from a (b) (4) to a (b) (4) in SE0000098
- Change in HPHC yields ranging from a (b) (4) to a (b) (4) in SE0000099
- Change in HPHC yields ranging from a (b) (4) in SE0000100

The review concludes that the differences in the package quantity, differences in tobacco blend, and (b) (4) in most[4] HPHCs do not cause the new products to raise different questions of public health. Based on the HPHC yields which were comparable or (b) (4) between the new and corresponding predicate tobacco products, the tobacco blend differences do not appear to negatively impact the composition of the new tobacco products. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Komal Singh on July 6, 2016, and December 20, 2016.

The applicant reported a small (b) (4) in the moisture content target specification for SE0000098. The other products contained no differences in design characteristics. An (b) (4) in moisture of the tobacco product may lead to (b) (4) in certain HPHCs. The applicant demonstrated that the HPHCs of concern were not (b) (4) in the new product than in the predicate product. The final engineering review concludes that the new tobacco products have different characteristics related to engineering compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health.

[3] For SE0000098, there was an overall (b) (4) of (b) (4) in the amount of tobacco leaf in the new product. For SE0000099, there was an overall (b) (4) of (b) (4) in the amount of tobacco leaf in the new product.
[4] In the cases in which the HPHC values are shown to (b) (4), those (b) (4) are all within the error of the analytical method.

4.3. MICROBIOLOGY

A microbiology review was completed by Almaris Alonso on December 29, 2016.

The microbiology review described several differences in microbial activity indicators including changes in pH on stability and difference in moisture content, but also showed (b) (4) in total microbial counts, and (b) (4) in HPHC contents that are the result of microbial growth. The applicant has adequately demonstrated that the changes in the microbial activity indicators did not lead to an (b) (4) in microbial growth or activity. The microbiology review concludes that the new tobacco products have different characteristics related to microbiology compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health.

4.4. SOCIAL SCIENCE

Social science reviews were completed by Elisabeth Donaldson on June 30, 2016 and by Rhonda Moore on January 4, 2017.

The first social science review concludes that the new tobacco products have different characteristics compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective.

The new tobacco products are in smaller package quantities than the corresponding predicate tobacco products. Given the small magnitude of the change (9% decrease), the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of substantial equivalence (SE) orders under section 910(a) of the FD&C Act for these provisional SE Reports is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA)[5] or an environmental impact statement (EIS). FDA has determined that there are no extraordinary circumstances requiring the preparation of an environmental assessment (EA).

[5] An environmental science review was completed on May 17, 2017 which identified deficiencies and a Preliminary Finding letter was issued on May 25, 2017. However, as explained above, the Preliminary Finding letter was rescinded on July 31, 2017.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- Decrease in package quantity by 9%
- Differences in tobacco blend (SE0000098 and SE0000099)
- (b) (4) in the yields of many HPHCs

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The changes in tobacco blend generally (b) (4) the HPHC yields of the new products. The other differences in characteristics between the new and predicate products were minor and would not cause the new products to raise different questions of public health. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

All of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued for the new tobacco products in SE0000098 - SE0000100, as identified on the cover page of this review.

FDA has found these tobacco products are substantially equivalent under section 910(a) of the FD&C Act and, therefore, issuance of SE orders for tobacco products that were on the market prior to March 22, 2011, is a class of action categorically excluded under 21 CFR 25.35(a), which does not require the preparation of an environmental assessment (EA) or an environmental impact statement (EIS).