Technical Project Lead (TPL) Review: SE0003404

SE0003404: Longhorn Long Cut Straight	
Package Type	Plastic Can with Plastic Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Cool/Sweet
Common Attributes of SE Reports	
Applicant	Swedish Match North America Inc.
Report Type	Provisional
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.04.21 12:14:39 -04'00'

Colleen K. Rogers, 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 Matthew R. Holman -S
Date: 2017.04.21 12:50:07 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco product:

SE0003404: Longhorn Long Cut Straight	
Product Name	Longhorn Long Cut Straight
Package Type	Plastic Can with Plastic Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Cool/Sweet

The predicate tobacco product is a smokeless loose moist snuff manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted a Substantial Equivalence (SE) Report on March 8, 2011. An acknowledgment letter was issued on July 28, 2011, and on December 14, 2012. The second acknowledgement letter included the package size to clarify which tobacco product was subject of the SE Reports. On December 31, 2012, FDA issued an Advice/Information request letter requesting additional information about the items that were identified to be deficient in the December 31, 2012, completeness review. In response, the applicant submitted an amendment with the requested information on January 24, 2013 (SE0006498). On January 13, 2016, FDA contacted the applicant regarding HPHC data. In response, the applicant submitted an amendment with the requested information on January 18, 2016 (SE0012796). On February 12, 2016, FDA contacted the applicant regarding their option to make a claim for categorical exclusion from environmental assessment. In response, the applicant submitted an amendment with a claim for categorical exclusion on February 18, 2016 (SE0012910). FDA issued an Advice/Information request letter on April 29, 2016, and in response the applicant submitted an amendment on May 6, 2016 (SE0013349). On July 22, 2016, and again on July 27, 2016, FDA contacted the applicant regarding corrections to the claim for categorical exclusion from environmental assessment. In response, the applicant submitted amendments on July 25, 2016, (SE0013538) and July 27, 2016 (SE0013544).

Product Name	SE Report	Amendments
Longhorn Long Cut Straight	SE0003404	SE0004654 SE0006498 SE0008261 SE0012796 SE0012910 SE0013349 SE0013538

Product Name	SE Report	Amendments
		SE0013544

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Administrative completeness reviews were completed by Stephanie Redus on December 31, 2012, and Joanna Randazzo on February 20, 2013.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated September 15, 2015, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

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 Tricia Johnson on January 25, 2016.

The chemistry review concludes that the new tobacco product has different characteristics related to product composition compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following issues related to product composition:

- The package quantity (i.e., quantity of tobacco in the package) decreased from 37.42 grams per can for the predicate tobacco product to 34.02 grams per can for the new tobacco product (9% decrease)

- (b) (4) respectively, in the new tobacco product compared to the predicate tobacco product
- (b) (4) in the new tobacco product compared to the predicate tobacco product

The new and predicate tobacco products are comprised of equal amounts of (b) (4) and have the same composition; however, the quantity of tobacco in the plastic can is decreased slightly in the new tobacco product (from 37.42 grams per can for the predicate tobacco product to 34.02 grams per can for the new tobacco product). The non-tobacco and packaging material ingredients are identical in both the new and predicate tobacco products. The moisture content, pH, and nicotine values are the same between the new and predicate tobacco products and do not alter the stability of the products. The applicant provided data for 18 harmful and potentially harmful constituents (HPHCs). All HPHC yields (b) (4) in the new tobacco product compared to the predicate tobacco product except for the following: (b) (4) Several tobacco-specific nitrosamines (TSNAs) were (b) (4) in the new tobacco product compared to the predicate tobacco product, including a (b) (4) in both (b) (4). Since TSNA yields (b) (4), this does not cause the new product to raise different questions of public health. The (b) (4) is not substantial from a chemistry perspective and does not cause the new product to raise different questions of public health. The primary concern with (b) (4) in a smokeless tobacco product is its effect on free nicotine quantities, by altering pH. However, the pH of the new and predicate tobacco products is the same, so the (b) (4) does not cause the new tobacco product to raise different questions of public health. The (b) (4) does not cause the new tobacco product to raise different questions of public health because it reflects expected variability in the analytical measurement combined with expected variability in the product. (b) (4) in smokeless tobacco products derives from the tobacco included in the products, since (b) (4) enters the tobacco plant from the surrounding soil. Because the tobacco blends are identical in the new and predicate tobacco products, the difference in (b) (4) levels represents the variability in (b) (4) uptake of the tobacco (i.e., agricultural variability). The (b) (4) are within analytical measurement variability and do not cause the new tobacco product to raise different questions of public health. Since the tobacco blend, quantities of additives, and packaging material ingredients are identical and the measured HPHC values and the stability of the loose moist snuff in the new and predicate tobacco products are comparable, the differences in characteristics and product composition between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to product composition.

4.2. SOCIAL SCIENCE

Social science reviews were completed by Joelle Robinson on January 26, 2016, and June 14, 2016.

The social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health related to consumer use and perception. The review identified the following issue related to consumer perception and use:

- The package quantity decreased from 37.42 grams per can in the predicate tobacco product to 34.02 grams per can in the new tobacco product (9% decrease)

It is possible that changes from larger to smaller package quantities might affect consumer perceptions and/or use of the tobacco product. Although there is no direct scientific evidence on the influence of loose moist snuff package quantity on consumer perceptions and/or use intentions, other scientific evidence suggests such changes may raise different questions of public health. Even though there is a 9% decrease in package quantity, it is unlikely that changes of this magnitude would raise different questions of public health. Therefore, the differences in product characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to consumer perception and use.

The review also evaluated the health information summary and determined that it did not violate section 911(b)(2)(A)(i)(II) of the FD&C Act. Therefore, the final review did not identify a deficiency related to the health information summary.

5. ENVIRONMENTAL DECISION

The applicant claims categorical exclusion from environmental assessment for this SE Report. FDA has reviewed the claims of categorical exclusion under 21 CFR 25.35(a). The new tobacco product is being evaluated under section 910(a)(2)(B) of the FD&C Act. If the new tobacco product remains on the market, there is no change to the environment. Issuance of SE orders is not anticipated to adversely affect a species or the critical habitat of a species as stipulated in 21 CFR 25.21(b). Therefore, FDA concludes that the categorical exclusion is warranted and no extraordinary circumstances exist which require preparation of an environmental assessment or an environmental impact statement (see 21 CFR 25.35(a)). A memo describing this environmental decision was signed by Kimberly Benson, Ph.D., on August 2, 2016.

6. CONCLUSION AND RECOMMENDATION

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

- The package quantity decreased from 37.42 grams per can for the predicate tobacco product to 34.02 grams per can for the new tobacco product (9% decrease)
- (b) (4) respectively, in the new tobacco product compared to the predicate tobacco product
- (b) (4) in the new tobacco product compared to the predicate tobacco product

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health.

It is possible that changes from larger to smaller package quantities might affect consumer perceptions and/or use of the tobacco product; however, it is unlikely that a 9% decrease in package quantity would raise different questions of public health. The tobacco blend, quantities of additives, and packaging material ingredients are identical between the new and predicate tobacco products and, from a chemistry perspective, the stability of the new and predicate tobacco products are comparable. The applicant provided HPHC yields for 18 constituents, including NNN and NNK. The quantity of HPHCs (b) (4) in the new tobacco product for all but four constituents, which were within expected variability and not significantly different. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

All of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the claim of categorical exclusion from environmental assessment and concluded that the categorical exclusion is warranted and no extraordinary circumstances exist which require preparation of an environmental assessment or an environmental impact statement.

An SE order letter should be issued for the new tobacco product in SE0003404, as identified on the cover page of this review.