



Technical Project Lead (TPL) Review: SE0011055

SE0011055: Longhorn Long Cut Mint	
Package Type	Plastic can with plastic lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Mint
Common Attributes of SE Report	
Applicant	Swedish Match North America, Inc.
Report Type	Product Quantity SE Report
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: 2017.06.14 11:51:41 -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: 2017.06.14 12:38:06 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product to compare with the new tobacco product below:

SE0011055: Longhorn Long Cut Mint	
Product Name	Longhorn Long Cut Mint
Package Type	Plastic can with plastic lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Mint

The predicate tobacco product is portioned moist snuff manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 27, 2015, FDA received a Product Quantity Change SE Report from the applicant. On May 7, 2015, FDA requested that the applicant provide information needed to uniquely identify the new and predicate tobacco products. In response, the applicant submitted an amendment with the requested information on May 12, 2015 (SE0011760). On March 31, 2016, FDA requested that the applicant provide clarifying information needed for the Environmental Assessment. In response, the applicant submitted an amendment with the requested information on April 7, 2016 (SE0013294).

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Idara Udoh on April 17, 2015, and by Jessica Kiser on June 14, 2017. The final review concludes that the SE Report includes information consistent with the recommendations in the December 2016 guidance "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)" and is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews 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 May 15, 2015, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE reviews, dated July 8, 2015, September 16, 2015, January 13, 2016, April 27, 2016, July 27, 2016, October 14, 2016, February 13, 2017, and April 21, 2017, conclude that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Anh Nguyen on July 31, 2015.

The final social science review concludes that the new tobacco product has different characteristics related to consumer perception and use compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The new and predicate tobacco products have the following difference in package quantity:

- Decrease from 37.42 g to 34.02 g (9%)

The review states that this magnitude of package quantity decrease is unlikely to affect consumer perception and use. Therefore, the differences in product characteristics related to consumer perception and use between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

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

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 18, 2016. The FONSI was supported by an environmental assessment prepared by FDA on November 18, 2016.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate products are identical except for the following package quantity changes:

- Decrease from 37.42 g to 34.02 g (9%)

The social science review concludes that these differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. I concur with the social science review.

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).

The new tobacco product is currently in compliance with the FD&C Act. I concur with the reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0011055 as identified on the cover page of this review.