FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0013001

SE0013001: Timber Wolf Long Cut Wintergreen	
Package Type	Plastic can and lid
Package Quantity	408.24 grams
Tobacco Cut Size	[redacted] CPI[1]
Characterizing Flavor	Wintergreen
Attributes of SE Report	
Applicant	Swedish Match USA, Inc.
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[1] Cuts per inch (CPI)

Technical Project Lead (TPL):

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Date: 2018.11.02 17:33:15 -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: 2018.11.05 08:59:13 -05'00'

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:

SE0013001: Timber Wolf Long Cut Wintergreen	
Product Name	Timber Wolf Long Cut Wintergreen
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	[redacted] CPI[1]
Characterizing Flavor	Wintergreen

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one SE Report on March 7, 2016, from Swedish Match North America, Inc, designated as a Product Quantity Change SE Report by the applicant. FDA issued an Acknowledgement letter on March 25, 2016. On September 7, 2017, FDA received a general correspondence from the applicant (TC0002691) informing FDA of an organizational restructure and company name change from Swedish Match North America, Inc to Swedish Match USA, Inc. FDA issued a Preliminary Finding (PFind) letter for environmental assessment issues on February 16, 2018. On March 16, 2018, FDA received an amendment (SE0014591) responding to the PFind letter. In the original application, the applicant designated the report as a Product Quantity Change SE Report, and included a certification statement to reflect that the only difference between the new and predicate tobacco products is the product quantity change. During review, FDA found differences in the container-closure system composition and packaging configuration between the new and predicate tobacco products. The applicant states that the new tobacco product is packaged with an empty can placed inside the container-closure system that consumers can refill themselves. Since the differences between the new and predicate tobacco products are not limited to a difference in product quantity, FDA reclassified the SE Report from a Product Quantity Change SE Report to a full SE Report.[2] On June 13, 2018, FDA issued an Advice/Information Request (A/I) letter requesting clarification of the packaging configuration of the empty can and a revised certification statement. On August 8, 2018, FDA received an amendment (SE0014846) responding to the A/I letter.

Product Name	SE Report	Amendments
Timber Wolf Long Cut Wintergreen	SE0013001	SE0014591 SE0014846

[2] See June 11, 2018, TPL memorandum "Deficiencies related to packaging composition and configuration for Swedish Match USA, Inc."

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Cecilia Robinson on March 25, 2016.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0013001 was previously determined to be substantially equivalent by FDA under SE0001762. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE reviews dated April 19, 2018, and October 16, 2018, conclude that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

The applicant states that the new tobacco product is packaged with an empty 34.02 gram can[3] that consumers can refill themselves thus, making the new tobacco product convenient to carry without disrupting the consumer's usual pattern of use. I note that the addition of the empty refillable can was not evaluated by the scientific reviewers so, as Technical Project Lead, I provide an evaluation here. The empty refillable can is wrapped in an 80-gauge orientated polypropylene film wrapper and placed within the container containing loose tobacco in the new tobacco product. Since the new tobacco product container is composed of the same type of plastic as the wrapper on the empty can (i.e., polypropylene), any effect of the plastic on the tobacco (if any) from the wrapper would be the same as from the container. Furthermore, this small difference in plastic polymer does not cause the new tobacco product to raise different questions of public health with respect to leachables and extractables. Therefore, the addition of the empty refillable can does not cause the new tobacco product to raise different questions of public health.

Also, although not evaluated by the scientific reviewers, the applicant provided the composition of the new and predicate tobacco product container-closure systems. The predicate tobacco product can is composed of polypropylene with a polypropylene lid and the new tobacco product container is composed of polypropylene with a linear low density polyethylene lid. Both polypropylene and linear low density polyethylene are thermoplastics composed of high molecular weight hydrocarbons (polyolefins). Given the similarities of these plastics, we do not expect the small change in plastics to affect product stability. In addition, the majority of the container-closure system (i.e., the can/container) is composed of the same plastic in the new and predicate tobacco

[3] The empty can has the same composition as the predicate tobacco product can: polypropylene can and lid.

products. Consequently, in this particular case, the change from a polypropylene lid to a linear low density polyethylene lid does not cause the new tobacco product to raise different questions of public health.

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

4.1. SOCIAL SCIENCE

Social science reviews were completed by Rhonda Moore on April 27, 2016, and by Jennifer Bernat on August 24, 2018.

The final social science review concludes that the new tobacco product has different characteristics from the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following differences:

- An increase in product quantity from 34.02 g to 408.24 g [1100%]
- Change in packaging configuration from a single can full of loose moist snuff in the predicate tobacco product to a larger container that includes a wrapped, empty refillable can[4] in the new tobacco product

The SE Report indicates a 1100% increase in product quantity. The final social science review cites an Office of Science (OS) memorandum[5] that summarizes OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Therefore, the differences in product quantity between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary. FDA has determined that the health information summary provided for this SE Report would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco product into interstate commerce.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Christine Modovsky on February 14, 2018, and April 6, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 7, 2018. The FONSI was supported by an environmental assessment prepared by FDA on August 7, 2018.

[4] The composition of the empty can is identical to the composition of the predicate tobacco product can and it is wrapped in an 80-gauge orientated polypropylene film wrapper.

[5] *See* memorandum on product quantity changes, dated December 7, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- 1100% increase in product quantity
- The new tobacco product contains an empty refillable 34.02 g can[4] within the container containing loose tobacco
- Change of container-closure system lid material from polypropylene to linear low density polyethylene

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. There is an 1100% increase in product quantity in the new tobacco product. The OS memorandum[5] concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion. Since the empty refillable can wrapper is composed of the same type of plastic as the new tobacco product container (polypropylene), this difference does not cause the new tobacco product to raise different questions of public health with respect to leachables and extractables, and any effect of the plastic on the tobacco (if any) from the wrapper would be the same as from the container. Therefore, the addition of the empty refillable can does not cause the new tobacco product to raise different questions of public health. For the change in container-closure system lid material, given the similarities of the plastics, we do not expect this small change in plastics to affect product stability. In addition, the majority of the container-closure system (i.e., the can/container) is composed of the same plastic in the new and predicate tobacco products. Consequently, in this particular case, the change from a polypropylene lid to a linear low density polyethylene lid does not cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0001762. Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

Comparison of the new tobacco product to the grandfathered tobacco product in SE0001762 (Timber Wolf Long Cut Wintergreen) reveals that the new tobacco product has the following differences in characteristics from Timber Wolf Long Cut Wintergreen, the grandfathered tobacco product:

- 1100% increase in product quantity
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from polypropylene to linear low density polyethylene
- Change in (b) (4)
- Addition o (b) (4)

- Lower quantities of total and free nicotine
- Lower quantities of tobacco-specific nitrosamines

The differences in (b) (4) listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0001762. Therefore, these differences do not cause the new tobacco product in SE0013001 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container closure-system lid material between the new tobacco product in SE0013001 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0013001 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act and I 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 SE0013001, as identified on the cover page of this review.