Technical Project Lead (TPL) Review: SE0012445 and SE0012446

SE0012445: Timber Wolf Pouches Wintergreen	
Package Type	Plastic can
Package Quantity	23.25 g (0.82 oz.)
Portion Count	15 pouches
Portion Mass	1.55 g per pouch
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4) cpi*
Characterizing Flavor	Wintergreen
SE0012446: Timber Wolf Pouches Natural	
Package Type	Plastic can
Package Quantity	23.25 g (0.82 oz.)
Portion Count	15 pouches
Portion Mass	1.55 g per pouch
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4) cpi*
Characterizing Flavor	Natural
Common Attributes of SE Reports	
Applicant	Swedish Match North America Inc.
Report Type	Regular Same Characteristics
Product Category	Smokeless Tobacco
Product Sub-Category	Portioned Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

* Cuts per inch (cpi)

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.12.30 22:29:19 -05'00'

For Colleen Rogers

Colleen K. Rogers, Ph.D.
Deputy 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: 2015.12.31 06:10:16 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0012445	**Timber Wolf Pouches Wintergreen**
Product Name	Timber Wolf Packs Wintergreen
Package Type	Plastic can
Package Quantity	23.25 g (0.82 oz.)
Portion Count	15 pouches
Portion Mass	1.55 g per pouch
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4) cpi*
Characterizing Flavor	Wintergreen
SE0012446	**Timber Wolf Pouches Natural**
Product Name	Timber Wolf Packs Natural
Package Type	Plastic can
Package Quantity	23.25 g (0.82 oz.)
Portion Count	15 pouches
Portion Mass	1.55 g per pouch
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4) cpi*
Characterizing Flavor	Natural

* Cuts per inch (cpi)

The predicate tobacco products are portioned smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 5, 2015, FDA received 2 Same Characteristics SE Reports from the applicant. On November 4, 2015, FDA requested that the applicant provide information needed to uniquely identify the new and predicate tobacco products. On November 9, 2015, the applicant submitted amendments SE0012587 and SE0012588 with the requested information. On December 8, 2015, FDA requested that the applicant provide information related to the environmental assessment. On December 14, 2015, the applicant submitted amendments SE0012726 and SE0012727 with the requested information.

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 Nabanita Nag on December 30, 2015. The reviews conclude that each SE Report includes all of the information recommended in the 2015 SE FAQ guidance document for a Same Characteristics SE Report:

1. The SE Reports are identified as "Same Characteristics SE Reports."
2. The new tobacco products are uniquely identified and manufactured by the applicant.
3. The predicate tobacco products are uniquely identified and manufactured by the applicant.
4. No SE Reports were previously submitted for the new tobacco products. The new tobacco products are currently marketed in the United States; however, FDA does not intend to object to commercial distribution of such products provided the Same Characteristics SE Reports meet all criteria outlined in the Final SE FAQ Guidance.[1]
5. There is a statement indicating that the applicant intends to market only the new tobacco products and not the predicate tobacco products.
6. An Environmental Assessment was provided.
7. A health information summary was provided, in accordance with section 910(a)(4) of the FD&C Act.
8. A statement explaining the applicant's actions to comply with any applicable standards under section 907 of the FD&C Act was provided.
9. An adequate certification statement that is signed by a responsible official who is authorized to act on behalf of the company was provided.

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 December 2015 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products based on a cross-reference to previously finalized standalone grandfathered reviews of the same products.

OCE also completed a review to determine whether the new tobacco products are 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 review dated

[1] The Final SE FAQ Guidance issued on March 4, 2015 and an updated version 2 was issued September 8, 2015.

December 4, 2015, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

The applicant submitted health information summaries, which were reviewed by social science. Additional scientific review was not initiated by the Office of Science (OS) because the characteristics of the new and predicate tobacco products are the same (i.e., the new and predicate products have identical characteristics). Therefore, additional scientific review is unnecessary.

4.1. SOCIAL SCIENCE

A social science review was completed by Wendy Slavit on November 19, 2015. The social science review evaluated the health information summaries and determined that they did not violate section 911(b)(2)(A)(i)(II) of the FD&C Act. Therefore, the review did not identify a deficiency related to the health information summaries.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 30, 2015. The FONSI was supported by an environmental assessment prepared by FDA on December 30, 2015.

6. CONCLUSION AND RECOMMENDATION

In all of the SE Reports, the product names differ between the new and corresponding predicate tobacco products, but the characteristics of the new and corresponding tobacco predicate products are the same, meaning identical in characteristics. The SE Reports include all of the information needed by FDA to make a substantial equivalence determination.

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).

The new tobacco products are currently in compliance with the FD&C Act. I concur with the reviews and recommend that SE order letters be issued.

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

SE order letters should be issued for the new tobacco products in SE0012445 and SE0012446, as identified on the cover page of this review.