

## Technical Project Lead (TPL) Review: SE0015504

SE0015504: Timber Wolf Pouches Peach	
Package Type	Plastic can and plastic lid
Package Quantity	23.25 g
Portion Count	15 pouches
Portion Mass	1.55 g
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Peach
Attributes of SE Report	
Applicant	Swedish Match USA, Inc.
Report Type	Regular
Product Category	Smokeless tobacco product
Product Sub-Category	Portioned moist snuff
Recommendation	
Issue Substantially Equivalent (SE) order.	

**Technical Project Lead (TPL):**

Digitally signed by Charles Feng -S  
Date: 2019.12.16 11:03:22 -05'00'

Charles Feng, 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: 2019.12.16 11:13:51 -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:

SE0015504: Timber Wolf Pouches Peach	
Product Name	Timber Wolf Pouches Wintergreen
Package Type	Plastic can and plastic lid
Package Quantity	23.25 g
Portion Count	15 pouches
Portion Mass	1.55 g
Portion Length	41 mm
Portion Width	17 mm
Portion Thickness	6 mm
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Wintergreen

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 19, 2019, FDA received a SE Report from Swedish Match USA, Inc. FDA issued an Acceptance letter to the applicant on September 24, 2019.

### 1.3. SCOPE OF REVIEW

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

## 2. REGULATORY REVIEW

A regulatory review was completed by Shireen Fotelargias on September 24, 2019.

The review concludes that the SE Report is administratively complete.

## 3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015504 was determined to be substantially equivalent by FDA under SE0012445. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed a review 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 review dated November 26, 2019, concludes that the new tobacco product is in compliance with the FD&C Act.

#### 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 Scott Wasdo on November 5, 2019.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry 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 differences:

- 5.3% (↓ (b) (4) mg/pouch) decrease in tobacco quantity
- Addition of peach flavor
- Removal of (b) (4) mg/pouch (b) (4)
- Addition of (b) (4) mg/pouch of (b) (4)
- 53% (↑ (b) (4) mg/pouch) increase in (b) (4)

The new and predicate tobacco products use the same tobacco blend and pouch materials, but each pouch of the new tobacco product has (b) (4) mg/pouch less tobacco (↓ 5.3%) than that of the predicate tobacco product, which is expected to reduce HPHC quantities. The applicant provided HPHC testing data indicating analytically equivalent quantities of acetaldehyde, arsenic, B[a]P, NNN and NNK as well as lower and non-equivalent quantities of cadmium, formaldehyde, and nicotine (total and free), which do not raise different questions of public health. The new and predicate tobacco products have different characterizing flavors (peach versus wintergreen). Consequently, the new tobacco product contains (b) (4) mg/pouch of peach flavor and (b) (4) mg/pouch of (b) (4) that are not present in the predicate tobacco product, and the predicate tobacco product contains (b) (4) (b) (4) mg/pouch that is not present in the new tobacco product. The replacement of (b) (4) with (b) (4) resulted in a net reduction of (b) (4) in the new tobacco product. Additionally, there is a 53% (↑ (b) (4) mg/pouch) higher quantity of (b) (4). The toxicological impact of changes in flavor ingredients is deferred to the toxicology review.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

##### 4.2. ENGINEERING

An engineering review was completed by Jimin Kim on October 24, 2019.

The engineering review did not identify any differences in characteristics between the new and predicate tobacco product that could cause the new tobacco product to raise different questions of public health from an engineering perspective.

#### 4.3. MICROBIOLOGY

A microbiology review was completed by Wen Lin on November 5, 2019.

The microbiology review concludes that the new tobacco product has different characteristics related to product microbiology 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 differences:

- 4% increase in (b) (4), a humectant
- Addition (b) (4) mg/g of (b) (4), a humectant
- 6% decrease in (b) (4), a preservative

The humectant and preservative differences between the new and predicate tobacco products could potentially affect microbial growth which in turn could affect the microbiological stability of the finished new tobacco product during storage. The applicant adequately addressed this concern by providing product stability data measured over the complete storage time (b) (4) of the new and predicate tobacco products. When compared to the predicate tobacco product, the total aerobic microbial count (TAMC) of the new tobacco product showed 2% and 7% increases at (b) (4) of storage but showed 51% decrease at (b) (4) of storage. The higher TAMC of the new tobacco product are not of concern because when compared to the predicate tobacco product, the new tobacco product showed lower nitrate (6% to 10%), nitrite (86% to 94%), NNN+NNK (20% to 37%) and total TSNA (23% to 40%) at all measured time points. Additionally, the new tobacco product showed decreases in NNN+ NNK (3%) and, total TSNA (9%) over the complete product storage time of (b) (4) when compared to the predicate tobacco product which showed increases in NNN+NNK (22%) and total TSNA (17%) over (b) (4). 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 from a microbiology perspective.

#### 4.4. TOXICOLOGY

A toxicology review was completed by Yanling Chen on October 28, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology 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 differences:

- 5.33% decrease in tobacco quantity
- Increase in (b) (4)
- Addition of (b) (4)
- Removal of (b) (4)
- Addition of a complex purchased peach flavor

The decreased amount of tobacco is expected to decrease HPHC quantities (see chemistry review for details). Although (b) (4) is increased and the peach flavor is added, their estimated daily intake or exposure is below the acceptable daily intake (ADI) values established by Joint FAO/WHO Expert Committee on Food Additives (JECFA), and therefore, are not expected to raise toxicological concerns. Furthermore, although (b) (4) is added, there is a net decrease of (b) (4) due to the removal of (b) (4). Therefore, the change in (b) (4) does not raise toxicological concern.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

#### 4.5. SOCIAL SCIENCE

A social science review was completed by Jennifer Alexander on December 6, 2019.

The social science review concludes that the new tobacco product has different characteristics related to social science 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 difference:

- Change in characterizing flavor from wintergreen to peach

The new tobacco product contains the characterizing flavor peach whereas the predicate tobacco product contains the charactering flavor wintergreen. Since the difference in flavor between the new and predicate tobacco products is not a change between non-characterizing and characterizing flavors, as indicated by use of flavor descriptors in the new and predicate tobacco products, based on current scientific evidence, this change in flavor does not cause the new tobacco product to raise different questions of public health beyond those of the predicate tobacco product, from a social science perspective.

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

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on October 30, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 5, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 5, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- 5.3% (↓<sup>(b) (4)</sup> mg/pouch) decrease in tobacco quantity
- Addition of peach flavor
- Removal of <sup>(b) (4)</sup> mg/pouch (b) (4)
- Addition of <sup>(b) (4)</sup> mg/pouch of (b) (4)
- 53% (↑<sup>(b) (4)</sup> mg/pouch) increase in (b) (4)
- 4% increase in (b) (4) a humectant
- Addition <sup>(b) (4)</sup> mg/g of (b) (4), a humectant
- 6% decrease in (b) (4), a preservative
- Change in characterizing flavor from wintergreen to peach

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The decreased amount of tobacco is not expected to increase HPHC quantities, which is confirmed by the HPHC data submitted for acetaldehyde, arsenic, B[a]P, cadmium, formaldehyde, NNN and NNK, and nicotine. Although (b) (4) and a peach flavor are increased or added, their estimated daily intake or exposure are below the ADI values established by JECFA, and therefore, are not expected to raise toxicological concerns. The replacement of (b) (4) with (b) (4) resulted in a net decrease of (b) (4), which is not of toxicological concern. Although there are changes in (b) (4) and (b) (4) (humectants) and a decrease in (b) (4) (preservative), the stability data showed decreases in TSNAs in the new tobacco product over the entire product storage time of 26 weeks. Therefore, these changes do not raise concerns from a microbiological perspective. Additionally, the new tobacco product contains the characterizing flavor peach whereas the predicate tobacco product contains the characterizing flavor wintergreen. Since the difference in flavor between the new and predicate tobacco products is not a change between non-characterizing and characterizing flavors, as indicated by use of flavor descriptors in the new and predicate tobacco products, based on current scientific evidence, this change in flavor does not cause the new tobacco product to raise different questions of public health beyond those of the predicate tobacco product from a social science perspective. Therefore, the differences in characteristics between the new and predicate tobacco product 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 SE0012445.



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 as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015504 was previously determined to be substantially equivalent by FDA under SE0012445. Comparison of the new tobacco product to the grandfathered tobacco product (Timber Wolf Packs Wintergreen in SE0012445) reveals that the new tobacco product has the following differences in characteristics from Timber Wolf Packs Wintergreen, the grandfathered tobacco product:

- 5.3% (b) (4) decrease in tobacco quantity
- Addition of peach flavor
- Removal of (b) (4) mg/pouch (b) (4)
- Addition of (b) (4) mg/pouch of (b) (4)
- 53% (↑ (b) (4) mg/pouch) increase in (b) (4)
- 4% increase in (b) (4), a humectant
- Addition (b) (4) mg/g of (b) (4), a humectant
- 6% decrease in (b) (4) a preservative
- Change in characterizing flavor from wintergreen to peach

The differences in characteristics listed above, are the same differences in characteristics identified for the new and predicate tobacco product in SE0015504. For the same reasons as discussed above, the differences between the new tobacco product in SE0015504 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 SE0015504 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. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product 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 letters 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 SE0015504, as identified on the cover page of this review.