



Technical Project Lead (TPL) Memorandum:

**SE Reports SE0001762, SE0003525, SE0003526,
SE0003528, SE0003529, SE0004386, SE0004387,
SE0004388**

SE0001762: Timber Wolf Long Cut Wintergreen	
Package Size	34.02 grams
Package Type	Plastic can
SE0003525: Renegade Long Cut Straight	
Package Size	34.02 grams
Package Type	Plastic can
SE0003526: Renegade Long Cut Wintergreen	
Package Size	34.02 grams
Package Type	Plastic can
SE0003528: Timber Wolf Long Cut Apple	
Package Size	34.02 grams
Package Type	Plastic can
SE0003529: Timber Wolf Long Cut Peach	
Package Size	34.02 grams
Package Type	Plastic can
SE0004386: Timber Wolf Long Cut Straight	
Package Size	34.02 grams
Package Type	Plastic can
SE0004387: Timber Wolf Long Cut Cool Wintergreen	
Package Size	34.02 grams
Package Type	Plastic can
SE0004388: Timber Wolf Fine Cut Wintergreen	
Package Size	34.02 grams
Package Type	Plastic can
Common Attributes of SE Reports	
Applicant	Swedish Match North America, Inc.
Report Type	Regular
Product Category	Smokeless tobacco product
Product Sub-Category	Loose moist snuff
Recommendation	
Issue Substantial Equivalence (SE) orders	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2013.11.14 23:10:05 -05'00'

Matthew R. Holman, 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 David Ashley -S
Date: 2013.11.15 07:04:07 -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:

Table 1. Predicate Tobacco Products

Timber Wolf Long Cut Wintergreen (SE0001762)	
Product Name	Timber Wolf Long Cut Wintergreen
Package Size	37.42 grams
Renegade Long Cut Straight (SE0003525)	
Product Name	Timber Wolf Long Cut Straight
Package Size	37.42 grams
Renegade Long Cut Wintergreen (SE0003526)	
Product Name	Timber Wolf Long Cut Wintergreen
Package Size	37.42 grams
Timber Wolf Long Cut Apple (SE0003528)	
Product Name	Timber Wolf Long Cut Apple
Package Size	37.42 grams
Timber Wolf Long Cut Peach (SE0003529)	
Product Name	Timber Wolf Long Cut Peach
Package Size	37.42 grams
Timber Wolf Long Cut Straight (SE0004386)	
Product Name	Timber Wolf Long Cut Straight
Package Size	37.42 grams
Timber Wolf Long Cut Cool Wintergreen (SE0004387)	
Product Name	Timber Wolf Long Cut Cool Wintergreen
Package Size	37.42 grams
Timber Wolf Fine Cut Wintergreen (SE0004388)	
Product Name	Timber Wolf Fine Cut Wintergreen
Package Size	37.42 grams

All of the predicate tobacco products are manufactured by Swedish Match North America, Inc. They are all loose moist snuff products sold in plastic cans.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the eight SE Reports listed in Table 2 of this memo. FDA sent the applicant administrative advice and information request letters (A/I letters) for these SE Reports. In response, the applicant submitted amendments to the SE Reports (see Table 2). The applicant also submitted unsolicited amendments (see Table 2). Following our review of the amended SE Reports, we sent a scientific A/I letter and a preliminary finding letter to the applicant in August 2012 and April 2013. The applicant responded to these letters by amending their SE Reports (see Table 2).

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
Timber Wolf Long Cut Wintergreen	SE0001762	SE0004186 SE0005053 SE0005090 SE0008185 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964
Renegade Long Cut Straight	SE0003525	SE0004240 SE0005320 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009874 SE0009910 SE0009964
Renegade Long Cut Wintergreen	SE0003526	SE0004207 SE0005321 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009874 SE0009910 SE0009964
Timber Wolf Long Cut Apple	SE0003528	SE0004212 SE0005055 SE0005092 SE0008187 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964

Product Name	SE Report	Amendments
Timber Wolf Long Cut Peach	SE0003529	SE0004221 SE0005056 SE0005093 SE0008188 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964
Timber Wolf Long Cut Straight	SE0004386	SE0004561 SE0005059 SE0005096 SE0008191 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964
Timber Wolf Long Cut Cool Wintergreen	SE0004387	SE0004561 SE0005060 SE0005097 SE0008192 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964
Timber Wolf Fine Cut Wintergreen	SE0004388	SE0004561 SE0005061 SE0005098 SE0008193 SE0008261 SE0008548 SE0009066 SE0009614 SE0009871 SE0009910 SE0009964

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0001762, SE0003525, SE0003526, SE0003528, SE0003529, SE0004386, SE0004387, and SE0004388.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The new tobacco product has the following key differences compared to the predicate tobacco product:

- Tobacco blend (all SE Reports)
- Lower total and free nicotine quantities (all SE Reports)
- Lower TSNA quantities (all SE Reports)
- Presence of (b) (4)
- (b) (4)

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by the following reviewers on the following dates:

- SE0001762: Marcella White, M.S., M.B.A., on January 13, 2012, and Stephanie Redus, M.S., on May 14, 2012
- SE0003525: Idara Udoh, M.S.A., on February 16, 2012, and Stephanie Redus, M.S. on October 30, 2012
- SE0003526: Marcella White, M.S., M.B.A., on January 13, 2012, and Stephanie Redus, M.S., on October 30, 2012
- SE0003528: Nathan Hurley on January 20, 2012, and Stephanie Redus, M.S., on May 15, 2012
- SE0003529: Sarah Lee, M.P.H., on January 26, 2012, and Stephanie Redus, M.S., on May 14, 2012
- SE0004386: Stephanie Redus, M.S., on May 23, 2012, and August 31, 2012
- SE0004387: Stephanie Redus, M.S., on May 23, 2012, and August 31, 2012
- SE0004388: Stephanie Redus, M.S., on May 23, 2012, and August 31, 2012

The final administrative completeness reviews concluded that these SE Reports are administratively complete.

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 April 9, 2012 for SE0001762, (b) (4) and SE0003529; June 5, 2012 for SE0004386-SE0004388; and June 19, 2012 for SE0003525 and SE0003526 conclude that the predicate tobacco products are eligible predicate tobacco products, as the applicant has established that the predicate tobacco products are grandfathered.¹

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the predicate 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 review dated November 5, 2013, concludes that the predicate 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

Chemistry reviews were completed for SE0001762, SE0003528, SE0003529, SE0004386, SE0004387, and SE0004388 by Michael Koenig, Ph.D. on August 9, 2012, Matthew Walters, Ph.D. on August 10, 2013, Brian Connell, Ph.D. on March 21, 2013, and Candice Jongsma, Ph.D. on July 22, 2013.

Chemistry reviews were completed for SE0003525 and SE0003526 by Michael Koenig, Ph.D. on September 24, 2012, Ciby Abraham, Ph.D. on March 21, 2013, and Candice Jongsma, Ph.D. on July 22, 2013.

The final chemistry review concludes that the new tobacco products do not raise different questions of public health with regard to product composition. The compositions of the new and corresponding predicate tobacco products are similar, but there are differences in tobacco blends and some other ingredients. These ingredient differences were accompanied by decreased quantities of tobacco-specific nitrosamines (TSNAs) in the new tobacco products compared to the corresponding predicate tobacco products. There are also decreased quantities of total and free nicotine in the new tobacco products compared to the corresponding predicate tobacco products. Based on the nature of the differences in blend, these HPHC data provide evidence that the product

¹ Addendum reviews were completed in 2013 to include the package type and size for the predicate and new tobacco products; the conclusions in these addendum reviews did not differ from that in the original 2012 reviews.

composition differences do not cause the new tobacco products to raise different questions of public health. The applicant also indicated that both the new and predicate tobacco products are stable for (b) (4). The product stability for both products is demonstrated by consistent moisture, pH, and flavor levels (b) (4) after manufacture.

4.2. ENGINEERING

Engineering reviews were completed for SE0001762, SE0003528, SE0003529, SE0004386, SE0004387, and SE0004388 by Sabina Reilly on June 26, 2012, James Melchiors on March 21, 2013, and Christian Coyle on July 22, 2013.

Engineering reviews were completed for SE0003525 and SE0003526 by Sabina Reilly on October 2, 2012, James Melchiors on March 21, 2013, and Christian Coyle on July 22, 2013.

The final engineering review concludes that the new tobacco products do not raise different questions of public health with regard to product design because the designs of the new and corresponding predicate tobacco products are identical.

4.3. TOXICOLOGY

Toxicology reviews were completed SE0001762, SE0003528, SE0003529, SE0004386, SE0004387, and SE0004388 by Michael Orr, Ph.D. on August 21, 2012, and April 8, 2013,

Toxicology reviews were completed SE0003525 and SE0003526 by Michael Orr, Ph.D., DABT on October 4, 2012.

The final toxicology review concludes that the new tobacco products do not raise different questions of public health with regard to product toxicity. The toxicology review focused on the following differences between the new and corresponding predicate tobacco products:

- Presence of (b) (4)
(b) (4)
- (b) (4)
- (b) (4)
- (b) (4)
- (b) (4)

An assessment was made concerning the differences in chemical constituents between the new and predicate products. For purposes of toxicological evaluation, in this case, we evaluated dietary intake levels and routes of exposure for orally consumed tobacco to determine whether current data could

be applied to make a decision concerning whether the differences cause the new product to raise different questions of public health. Since for these smokeless tobacco products the routes of exposure (buccal and gastrointestinal absorption) are the same as for food, information about the ingredients listed above in foods was used to inform the toxicity of these ingredients in the new tobacco products. The presence of (b) (4) in the new tobacco product does not raise toxicity concerns because the level of exposure is below the adult daily intake (ADI) set by the United Nations Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA). Furthermore, both the European Food Safety Authority (EFSA) and FDA have found (b) (4) safe for use in food and beverages. (b) (4)

(b) (4)

The applicant provided evidence that the levels of (b) (4)

(b) (4)

indicated that (b) (4) The applicant also

(b) (4) The toxicologist found that the quantities of (b) (4) in the new products are not significantly (b) (4) than those in the corresponding predicate products. Therefore, the toxicology review concludes that the new tobacco products do not raise different questions of public health.

4.4. SOCIAL SCIENCE

Social science reviews were completed by Greta Tessman on July 18, 2012, and January 15, 2013, and Abigail Prestin on August 29, 2013, and September 27, 2013.

The final social science review concludes that the new tobacco products do not raise different questions of public health with regard to product appeal. The review considered whether the darker color of the new tobacco products compared to the corresponding predicate tobacco products increases the appeal of the new tobacco products. The SE Reports included information about consumer perception testing that was performed, but the submitted information did not address the specific color differences between the new and corresponding predicate products. At this time, the available scientific evidence is not sufficient to establish that the product color differences in this case are significant enough to cause the new tobacco products to raise different questions of public health. The applicant provided a health information summary in compliance with section 910(a)(4) of the FD&C Act. The review concludes that the summary is acceptable. Overall, the social science review concludes that the

differences in product appeal between the predicate and corresponding new tobacco products are such that the new tobacco products do not raise different questions of public health.

4.5. ADDICTION

An addiction review was completed by Elena Mishina on August 15, 2013.

The addiction review concludes that the new tobacco products do not raise different questions of public health with regard to the likelihood of increased initiation and decreased cessation. The total and free (unprotonated) nicotine quantities are lower in the new tobacco products than the corresponding predicate tobacco products. The addictiveness of the new and predicate tobacco products appear to be similar because the free nicotine quantity in the new tobacco products is not likely to appeal to different users. More specifically, the lower free nicotine quantity is not likely to appeal to new users, who tend to prefer low free nicotine quantities when initiating use, because the free nicotine quantity in the new tobacco products is still in the same range as that for the corresponding predicate tobacco products. Therefore, the addiction review concludes that the differences in the likelihood of increased initiation and decreased cessation between the predicate and new tobacco products are such that the new tobacco products do not raise different questions of public health.

5. ENVIRONMENTAL DECISION

An environmental assessment was provided by the applicant. A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on November 14, 2013. The FONSI was supported by an environmental assessment prepared by Hoshing Chang, Ph.D. and Ronald Edwards, M.S. dated November 14, 2013.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and corresponding predicate tobacco products consist primarily of the following:

- Tobacco blend (all SE Reports)
- Lower total and free nicotine quantities (all SE Reports)
- Lower TSNA quantities (all SE Reports)
- Presence of (b) (4)
- (b) (4)

Although there are differences in the tobacco blend and other ingredients in the new tobacco products compared to the corresponding predicate tobacco products, those differences do not cause the new tobacco products to raise different questions of public health. The HPHC data indicates that these differences in characteristics do not cause the new tobacco products to be more toxic than the corresponding predicate tobacco products. More specifically, the TSNA quantities in the new tobacco products are lower than those in the corresponding predicate tobacco products, which does not cause the new tobacco products to raise different questions of public health. In addition, there is a slight but statistically significant decrease in free nicotine quantity in the new tobacco products compared to the corresponding predicate tobacco products. The decrease is not likely to increase the appeal of the new tobacco products because the free nicotine quantities in the new and corresponding predicate tobacco products are both in the same range, meaning that inexperienced and experienced users are not more likely to use that new tobacco product than the predicate tobacco product.

An assessment was made concerning the differences in chemical constituents between the new and predicate products. For purposes of toxicological evaluation, in this case, we evaluated dietary intake levels and routes of exposure for orally consumed tobacco to determine whether current data could be applied to make a decision concerning whether the differences cause the new product to raise different questions of public health. Since for these smokeless tobacco products the routes of exposure (buccal and gastrointestinal absorption) are the same as for food, information about the ingredients listed above in foods was used to inform the toxicity of these ingredients in the new tobacco products. The presence of (b) (4) (b) (4) in the new tobacco product does not raise toxicity concerns because the level of exposure is below the adult daily intake (ADI) set by the United Nations Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA). Furthermore, both the European Food Safety Authority (EFSA) and FDA have found (b) (4) safe for use in food and beverages.

(b) (4)

(b) (4) The applicant provided evidence that the levels of (b) (4)

(b) (4) The applicant also indicated that (b) (4)

(b) (4) The toxicologist found that the quantities of (b) (4) in the new products are not significantly (b) (4) than those in the corresponding predicate products. Therefore, the toxicology review concludes that the new tobacco products do not raise different questions of public health.

TPL Memorandum for SE0001762, SE0003525, SE0003526, SE0003528, SE0003529, SE0004386, SE0004387, SE0004388

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. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

In addition, order letters can be issued because 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 SE0001762, SE0003525, SE0003526, SE0003528, SE0003529, SE0004386, SE0004387, and SE0004388, as identified on the cover page of this memo.