FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review:

# SE0014130 - SE0014132

| SE0014130: Rooster Long Cut Mint | |
|---|---|
| Package Type | Plastic Can with Metal Lid |
| Package Quantity | 34.02 g |
| Tobacco Cut Size[1] | (b)(4) cpi |
| Characterizing Flavor | Mint |
| **SE0014131: Red Seal Fine Cut** | |
| Package Type | Plastic Can and Lid |
| Package Quantity | 42.53 g |
| Tobacco Cut Size[1] | (b)(4) cpi |
| Characterizing Flavor | None |
| **SE0014132: Rooster Long Cut Wintergreen** | |
| Package Type | Plastic Can with Metal Lid |
| Package Quantity | 34.02 g |
| Tobacco Cut Size[1] | (b)(4) cpi |
| Characterizing Flavor | Wintergreen |
| **Common Attributes of SE Reports** | |
| Applicant | U.S. Smokeless Tobacco Company, LLC |
| Report Type | Regular |
| Product Category | Smokeless Tobacco Product |
| Product Sub-Category | Loose Moist Snuff |
| **Recommendation** | |
| Issue Substantially Equivalent (SE) orders. | |

[1] Applicant did not provide cut size information for the new tobacco products. The second Engineering review notes that in lieu of cut size specifications, the applicant provided adequate information to demonstrate the cut size is similar for the new and corresponding predicate products.

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S
Date: 2018.05.23 16:31:45 -04'00'

Kenneth M. Taylor, Ph.D.
DPS 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: 2018.05.24 09:31:40 -04'00'

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

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# 1. BACKGROUND

## 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

| SE0014130: Rooster Long Cut Mint | |
|---|---|
| Product Name | Rooster Long Cut Mint (GF1200065) |
| Package Type | Plastic Can and Lid |
| Package Quantity | 34.02 g |
| Tobacco Cut Size | (b)(4) cpi |
| Characterizing Flavor | Mint |
| **SE0014131: Red Seal Fine Cut** | |
| Product Name | Red Seal Fine Cut Natural (GF1200202) |
| Package Type | Plastic Can and Lid |
| Package Quantity | 42.53 g |
| Tobacco Cut Size | (b)(4) cpi |
| Characterizing Flavor | None |
| **SE0014132: Rooster Long Cut Wintergreen** | |
| Product Name | Rooster Long Cut Wintergreen (GF1200066) |
| Package Type | Plastic Can and Lid |
| Package Quantity | 34.02 g |
| Tobacco Cut Size | (b)(4) cpi |
| Characterizing Flavor | Wintergreen |

The predicate tobacco products are loose moist snuff smokeless tobacco products manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received three SE Reports on June 2, 2017, submitted by Altria Client Services Inc. (ALCS) on behalf of U.S. Smokeless Tobacco Company LLC (USSTC). FDA issued Acknowledgement letters on June 21, 2017. FDA issued Advice/Information Request letters (A/I letters) for all STNs on August 25, 2017. On October 24, 2017, FDA received responses (SE0014389) to the AI letter. FDA issued a Preliminary Finding (PFind) letter on January 22, 2018. On February 20, 2018, the applicant responded (SE0014540) to FDA's PFind letter for SE0014130-14132.

| Product Name | SE Report | Amendments |
|---|---|---|
| Rooster Long Cut Mint | SE0014130 | SE0014389<br>SE0014540 |
| Red Seal Fine Cut | SE0014131 | |

| | | |
|---|---|---|
| Rooster Long Cut Wintergreen | SE0014132 | |

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

## 2. REGULATORY REVIEW

A regulatory review was completed by Sara Hernandez on June 21, 2017.

The review concludes that the 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated July 27, 2017, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco 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 June 8, 2018, concludes that the new tobacco products are 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

The chemistry review was completed by An Vu on August 15, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Addition of trace amounts of two lid coating ingredients ((b) (4) [redacted]) in the new tobacco products in SE0014130 and SE0014132
- Replacement of (b) (4) [redacted] with (b) (4) [redacted] as an ingredient in the new tobacco product in SE0014131

The applicant uses the two lid ingredients in trace amounts in more than 90% of its smokeless tobacco products that it sells in the United States. Furthermore, the change to (b) (4) involves an ingredient change that is present at only 0.0001mg/g of the consumed product. These ingredient differences involve ingredients that are present at very small and negligible amounts. As a result, the ingredient changes in the new tobacco products do not cause the new tobacco products to raise different questions of public health.

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

## 4.2. ENGINEERING

Engineering reviews were completed by Komal Ahuja on August 16, 2017, and December 15, 2017, and by Robert Meyer on April 2, 2018.

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

## 4.3. MICROBIOLOGY

Microbiology reviews were completed by Wen Lin on August 15, 2017, and by Prashanthi Mulinti on December 17, 2017.

The final microbiology review concludes that the new tobacco products have different characteristics related to product microbiology compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- For SE0014130 and SE0014132, change in container-closure system: plastic can with metal lid in the new tobacco product as opposed to plastic can with plastic lid in the predicate tobacco product.

The applicant submitted measurements for pH, oven volatiles (OV%), water activity, nitrate, nitrite, NNN, NNK, and total tobacco-specific nitrosamines (TSNAs) for the new tobacco products in SE0014130 and SE0014132. The pH, OV% and water activity levels showed little variation between the new and corresponding predicate tobacco products in SE0014130 and SE0014132. The pH of the new tobacco products in SE0014130 and SE0014132 decreased during the storage time of the product.

For the new tobacco product in SE0014130, there are small increases of 2% and 3% for NNN and nitrate respectively with time, whereas the new tobacco product in SE0014132 showed decreases (≤ 15%) in NNN, NNK and total TSNA values during product storage. In addition, the

new tobacco products in SE0014130 and SE0014132 showed minor variations (≤ 3%) in the levels of nitrate, NNN, NNK and total TSNAs in comparison to the corresponding predicate tobacco product at each shelf life time point. These small variations in TSNA levels of the new tobacco products in comparison to the corresponding predicate tobacco products are not of concern and do not cause the new tobacco products to raise different questions of public health from a microbiology perspective. For SE0014130, the applicant provided data for nitrite, nitrate, NNN, NNK and total TSNA levels measured at the beginning, middle and end of shelf life for only the predicate tobacco product. The applicant did not provide new tobacco product TSNA data, so a comparison of the new and predicate tobacco products over time could not be made. The nitrite levels of the predicate tobacco product are below the limit of detection (2µg). The nitrate, NNN, NNK and total TSNA levels of the predicate tobacco product decreased (≤ 12%) over the product storage time. These changes are minor and not of concern from a microbiology perspective. Since the new tobacco product composition in SE0014130 differs only in the type of an oil ingredient ((b) (4)) when compared to the predicate tobacco product ((b) (4)), the nitrate, nitrite, NNN, NNK and total TSNA data of the predicate tobacco product can be extrapolated to the new tobacco product. The lack of TSNA data for the new tobacco product in SE0014130 is not of concern and does not cause the new tobacco product to raise different questions of public health from a microbiology perspective.

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

### 4.4. TOXICOLOGY

Toxicology reviews were completed by La'Nissa Brown-Baker on August 16, 2017, and January 3, 2018.

The final toxicology review concludes that the new tobacco products have different characteristics related to product toxicology compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- For SE0014131, substitution of "(b) (4)" with (b) (4) In the new tobacco product.
- For SE0014130 and SE0014132, addition of trace amounts of (b) (4) and (b) (4) in the new metal can lid in the new tobacco products

For SE0014131, the new tobacco product uses (b) (4) in place of (b) (4), which is used in the corresponding predicate tobacco product. The applicant provided a detailed listing of the composition of (b) (4) based on their specifications in terms of percent of each subcomponent in the formula (not mass quantity), and the values were evaluated. The substitution in ingredients does not raise different toxicological concerns.

SE0014130 and SE0014132 indicate that the new metal lid interior packaging of the new products contains added "(b) (4)" and "(b) (4)" at "trace amounts" or "trace possible" levels. The applicant provided data and scientific evidence to define trace amounts of these materials. The applicant completed testing of (b) (4) as

defined in 21 CFR 175.300 to mitigate the potential introduction and leaching into the new tobacco product. Therefore, the use of (b) (4) for packaging the new tobacco products does not raise different questions of public health. The other complex ingredient, "(b) (4) ," is generally recognized as safe (GRAS) when used under certain conditions according to 21 CFR 178.3700. FDA requires that petrolatum used in food packaging or drugs meet impurity restrictions for polycyclic aromatic hydrocarbons (21 CFR 172.880). (b) (4) company (owner of (b) (4) ®) Specification Sheet [1] states that "(b) (4) is a (b) (4) Petrolatum USP meeting requirements for USP [USP29-NF24, Page 1693 (current revision)] and FDA requirements (21 CFR 172.880)". Thus, "(b) (4) " meets FDA standards for food packaging or drugs and while these regulations do not directly apply to tobacco products, the specifications do inform understanding of the possible toxicity of chemicals contained in tobacco products used orally. Because (b) (4) is a non-reactive food grade oil used as a processing aid and migration of the material into the moist environment of the smokeless tobacco product is unlikely, the use of (b) (4) does not cause the new product to raise different questions of public health from a toxicology perspective.

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

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Hans Rosenfeldt, Ph.D. on May 17, 2018. The FONSI was supported by an environmental assessment prepared by FDA on May 17, 2018.

## 6. CONCLUSION AND RECOMMENDATION

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

- SE0014130 and SE0014132: Change in container-closure system from a plastic can with plastic lid in the predicate tobacco products to a plastic can with metal lid in the corresponding new tobacco products
- SE0014130 and SE0014132: Addition of trace amounts of two lid coating ingredients ((b) (4) and (b) (4) ) in the new tobacco products that are not present in the corresponding predicate tobacco products
- SE0014131: Replacement of (b) (4) with (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The change in the container closure system could affect the microbial activity in the new tobacco products compared with the corresponding predicate tobacco products. However, based upon the data provided by the applicant for pH, OV%, water activity, nitrate, nitrite, NNN, NNK, and total TSNAs for the new and corresponding predicate tobacco products, the change from a plastic lid to a metal lid in the new tobacco products does not appear to affect microbial activity. Similarly, the additions of (b) (4) and (b) (4) in the metal lids for the new tobacco products are

consistent with food packaging standards. The applicant completed testing of [redacted] to mitigate the potential introduction and leaching into the new tobacco product. Furthermore, [redacted] is a non-reactive food grade oil used as a processing aid and migration of the material into the moist environment of the smokeless tobacco product is unlikely. Last, the substitution of [redacted] for [redacted] does not cause the new tobacco products to raise different questions of public health due to the very small amount used in the new tobacco products. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets 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.

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 SE0014130, SE0014131, and SE0014132, as identified on the cover page of this review.