FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0000083, SE0000088, SE0000089, SE0000091, and SE0000101

SE0000083: Granger Select 3 oz.	
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000088: J.D.'s Blend 3 oz.	
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000089: Southern Pride 3 oz.	
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000091: Timber Wolf Long Cut Wintergreen 34.02 g	
Package Type	Plastic Can and Lid
Tobacco Cut Size	(b) (4) CPI
Package Quantity	34.02 g
Characterizing Flavor	Wintergreen
Additional Property	Long Cut
SE0000101: Longhorn Fine Cut Wintergreen 34.02g	
Package Type	Plastic Can and Lid
Tobacco Cut Size	(b) (4) CPI
Package Quantity	34.03 g
Characterizing Flavor	Wintergreen
Additional Property	Fine Cut
Common Attributes of SE Reports	
Applicant	Swedish Match USA, Inc.
Report Type	Provisional
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Chewing Tobacco (SE0000083, SE0000088, and SE0000089) Moist Snuff (SE0000091 and SE0000101)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.03.01 10:29:19 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
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 Matthew R. Holman -S
Date: 2018.03.01 11:24:09 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0000083: Granger Select 3 oz.	
Product Name	Granger Select
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000088: J.D.'s Blend 3 oz.	
Product Name	J.D.'s Blend
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000089: Southern Pride 3 oz.	
Product Name	Southern Pride
Package Type	Pouch
Package Quantity	3 oz.
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	None
SE0000091: Timber Wolf Long Cut Wintergreen 34.02 g	
Product Name	Timber Wolf Long Cut Wintergreen 37.42 g
Package Type	Plastic Can and Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
Additional Property	Long Cut
SE0000101: Longhorn Fine Cut Wintergreen 34.02g	
Product Name	Longhorn Fine Cut Wintergreen 37.42 g
Package Type	Plastic Can and Lid
Package Quantity	37.42 g
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
Additional Property	Fine Cut

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received five provisional SE Reports from Swedish Match USA, Inc. (SMUSA) on March 10, 2011 as indicated above and subsequently issued Acknowledgment letters on July 19, 2011. On July 5, 2012, FDA received the Environmental Assessments as an unsolicited amendment (SE0004654) for SE0000083, SE0000088, SE0000089, SE0000091, and SE0000101. FDA issued Advice/Information Request letters (A/I letters) for SE0000083 and SE0000091 on November 21, 2012. On December 17, 2012, FDA received the applicant's responses (SE0005324 and SE0005328) to the A/I letters for SE0000083 and SE0000091. FDA issued A/I letters for SE0000088, SE0000089, and SE0000101 on December 27, 2012. On January 25, 2013, FDA received the applicant's responses (SE0006479, SE0006480, and SE0006491) to the A/I Request letters for SE0000088, SE0000089, and SE0000101. FDA sent an email (teleconference request) on April 17, 2013 to request additional information about the applicant's predicate products for the above SE Reports. On April 23, 2013, FDA received the applicant's response (SE0008261) to the email as an amendment with a spreadsheet containing the predicate product information for the above SE Reports. FDA sent an email request on October 30, 2013 asking the applicant to clarify the provisional product relationship for SE0000091. On November 1, 2013, FDA received the applicant's response (SE0009964). FDA issued a Notification letter on August 11, 2015 informing the applicant of FDA's intent to begin scientific review on September 25, 2015. FDA issued an A/I letter for the above SE Reports on August 25, 2017. On October 10, 2017, FDA issued a Correction letter to remove deficiency #17 from the A/I letter, which referenced the packaging of the new product versus the predicate product and how that may affect the appeal of the product. On October 23, 2017, FDA received the applicant's response (SE0014390) to the A/I letter for the above SE Reports.

Product Name	SE Report	Amendments
Granger Select 3 oz.	SE0000083	SE0004654 SE0005324 SE0008261 SE0014390
J.D.'s Blend 3 oz.	SE0000088	SE0004654 SE0006479 SE0008261 SE0014390
Southern Pride 3 oz.	SE0000089	SE0004654 SE0006480 SE0008261 SE0014390
Timber Wolf Long Cut Wintergreen 34.02 g	SE0000091	SE0004654 SE0005328 SE0008261 SE0009964 SE0014390

Product Name	SE Report	Amendments
Longhorn Fine Cut Wintergreen 34.02g	SE0000101	SE0004654 SE0005324 SE0008261 SE0014390

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Completeness reviews were completed by Stephanie Redus on November 21, 2012 and by Joanna Randazzo on February 15, 2013 for SE0000083 and SE0000091; by Stephanie Redus on December 27, 2012 and Joanna Randazzo on February 15, 2013 for SE0000088 and SE0000089; and by Stephanie Redus on December 27, 2012 and Joanna Randazzo on February 20, 2013 for SE0000101.

The final reviews conclude 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 as of February 15, 2007). The OCE reviews dated September 15, 2015 and February 23, 2018, 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.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Jeffrey Ammann on January 13, 2016, and by Changyu Chae on December 22, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition 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 issues related to product composition:

- For SE0000088, (b) (4) [redacted] was (b) (4) [redacted] higher in the new product compared to the predicate product

- For SE0000091, (b) (4) was (b) (4) higher and (b) (4) was (b) (4) lower in the new product compared to the predicate product
- For SE0000083 and SE0000089, unmodified corn starch was present in the new products (at (b) (4) mg/g and (b) (4) mg/g, respectively) while the corresponding predicate products did not contain unmodified corn starch
- For all SE Reports, the HPHC levels (including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN) were lower in the new products or minimally increased (no more than 4% higher) than in the corresponding predicate products
- For SE0000083 and SE0000089, the complex flavor (b) (4), was higher in the new products when compared to corresponding predicate products by (b) (4) and (b) (4) respectively[1]

For all SE Reports, the differences in tobacco blend and other ingredients do not result in increased HPHC levels in the new tobacco products compared to the corresponding predicate tobacco products. 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 composition.

4.2. ENGINEERING

Engineering reviews were completed by Erdit Gremi on January 13, 2016, and by Julie Morabito on December 21, 2017.

The final engineering review concludes that the new tobacco products have different characteristics related to product design 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 issues related to product design:

- For SE0000101, minor increase (b) (4) in final tobacco moisture

The applicant provided all the necessary target specifications, upper and lower range limits, and test data for the engineering design parameters needed to characterize the new and predicate tobacco products. The applicant provided the necessary information to demonstrate that there are no substantial differences with respect to engineering for the new and predicate products for all SE Reports. 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 design.

4.3. MICROBIOLOGY

Microbiology reviews were completed by Almaris Alonso on January 26, 2016 and December 21, 2017.

[1] The 3rd chemistry review indicated that deficiency 5 of the Preliminary Finding letter was not resolved, however, this was a typo as this deficiency was resolved as the applicant provided sufficient information explaining the meaning of N/A and the reporting of "mg/unit of use."

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 issues related to product microbiology:

- SE0000083
  - Increases in NNN+NNK (≤ 11%) and total TSNA (≤ 17%) levels in the new product compared to the predicate product during the product storage period[2]
  - Increase (b) (4) in preservative levels in the new product compared to the predicate product
  - Lower TAMC[3] from the new product compared to the predicate product during the product storage period
  - Lower TYMC[4] from the new product compared to the predicate product at the beginning (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000088
  - Decreases in NNN+NNK (≤ 27%) and total TSNA (≤ 21%) levels in the new product compared to the predicate product over the product storage period[2]
  - Lower TAMC from the new product compared to the predicate product during the product storage period[2]
  - Lower TYMC from the new product compared to the predicate product at the beginning (≤ (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000089
  - Decreases in NNN+NNK (≤ 32%) and total TSNA (≤ 23%) levels in the new product compared to the predicate product over the product storage period
  - Increase (≤ (b) (4) in preservative levels in the new product compared to the predicate product
  - Lower TAMC from the new product compared to the predicate product during the product storage period
  - Lower TYMC from the new product compared to the predicate product at the beginning (≤ (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000091
  -
  - Decreases in NNN+NNK (≤ 26%) and total TSNAs (≤ 30%) levels in the new product compared to the predicate product over the product storage period

[2] The product storage includes the beginning, middle, and end of the measured time course
[3] TAMC: total aerobic microbial count
[4] TYMC: total combined yeasts and molds count

- SE0000101
  - Increases in NNN+NNK (≤ 36%) and total TSNA (≤ 45%) levels in the new product compared to the predicate product during the product storage period
  - Decreases in NNN+NNK (≤ 26%) and total TSNAs (≤ 30%) levels in the new product compared to the predicate product over the product storage period

The applicant provided stability data for pH, moisture content (OV%), NNN, NNK, total TSNAs measured over the storage time of the new and corresponding predicate tobacco products. The pH and moisture data of the new tobacco products showed little variation compared to the corresponding predicate tobacco products and over product storage time. The applicant provided TYMC data that showed low (b) (4) cfu/g) yeast and mold counts over the storage time of the products. The new tobacco products in SE0000083, SE0000088 and SE0000089 showed lower TAMC in comparison to the corresponding predicate tobacco products at the beginning, middle and end of product storage time. In addition, the TYMC of these new tobacco products were either (b) (4) or lower in comparison to the corresponding predicate tobacco products. For all SE Reports, the levels of NNN+NNK and TSNAs decreased in the new tobacco products over product storage time. The new tobacco products in SE0000083 and SE0000101 showed increases in NNN+NNK and total TSNA levels at specific time points of product storage time compared to the corresponding predicate tobacco products. However, this increase is not of concern given the decrease in the levels of NNN+NNK and total TSNAs over the full storage time of the new tobacco products. 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 microbiology.

4.4. TOXICOLOGY

Toxicology reviews were completed by James Hobson on March 10, 2016 and Dana Lauterstein on January 4, 2018.

The final toxicology review concludes that the new tobacco products have different characteristics related to 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 issues related to toxicology:

- For SE0000083 and SE0000089, (b)(4) were either added or increased in new products as compared to their corresponding predicate products
- For SE0000088, (b) (4) was (b) (4) higher in the new product compared to the predicate product
- For SE0000091, (b) (4) was (b) (4) higher and (b) (4) was (b) (4) lower in the new product compared to the predicate product
- For all SE Reports, the HPHC levels (including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN) were lower in the new products or minimally increased (no more than 4% higher) than in the corresponding predicate products

For all SE Reports, the differences in tobacco blend and other ingredients do not result in increased HPHC levels in the new tobacco products compared to the corresponding predicate tobacco products. 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 toxicology.

4.5. SOCIAL SCIENCE

Social science reviews were completed by Joelle Robinson on January 27, 2016, and by Rhonda Moore on December 22, 2017.

The final social science review concludes that the characteristics which may affect consumer perception and use are the same for the new and corresponding predicate tobacco products. The review also evaluated the health information summary for each SE Report. FDA has determined that statements provided for these SE Reports which are required in a health information summary pursuant to section 910(a)(4) of the FD&C Act do not constitute modified risk claims. The applicant's health information summary for each new tobacco product does not potentially violate section 911.

5. ENVIRONMENTAL DECISION

The new tobacco products are being evaluated under section 910(a)(2)(B) of the FD&C Act. Under 21 CFR 25.35(a), issuance of SE orders for new tobacco products evaluated under section 910(a)(2)(B) of the FD&C Act falls within a class of actions that are ordinarily categorically excluded from the preparation of an environmental assessment (EA) or an environmental impact statement (EIS). The SE orders are in compliance with the categorical exclusion criteria. To the best of our knowledge, no extraordinary circumstances exist that would preclude application of this categorical exclusion. FDA concludes that categorical exclusion is warranted and no EA or EIS is required.

6. CONCLUSION AND RECOMMENDATION

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

- SE0000083
  - (b)(4) was present in the new products (at (b) (4) mg/g and (b) (4) mg/g, respectively) while the corresponding predicate products did not contain (b)(4)
  - Complex flavor (b) (4), was higher in the new product when compared to corresponding predicate product by (b) (4)
  - The HPHCs including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN showed a reduction in these HPHCs between the new and predicate product or minimal increases of no more than 4%

  - Increases in NNN+NNK (≤ 11%) and total TSNA (≤ 17%) levels in the new product compared to the predicate product during the product storage period
  - Increase (≤ (b) (4) in preservative levels in the new product compared to the predicate product
  - Lower TAMC from the new product compared to the predicate product during the product storage period
  - Lower TYMC from the new product compared to the predicate product at the beginning (≤ (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000088
  - (b) (4) was (b) (4) higher in the new product compared to the predicate product
  - The HPHCs including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN showed a reduction in these HPHCs between the new and predicate product or minimal increases of no more than 4%
  - Decreases in NNN+NNK (≤ 27%) and total TSNA (≤ 21%) levels in the new product compared to the predicate product over the product storage period[2]
  - Lower TAMC from the new product compared to the predicate product during the product storage period[2]
  - Lower TYMC from the new product compared to the predicate product at the beginning (≤ (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000089
  - (b)(4) was present in the new product (at (b) (4) mg/g and (b) (4) mg/g, respectively) while the corresponding predicate product did not contain (b)(4)
  - Complex flavor (b) (4), was higher in the new product when compared to corresponding predicate product by (b) (4)
  - The HPHCs including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN showed a reduction in these HPHCs between the new and predicate product or minimal increases of no more than 4%
  - Decreases in NNN+NNK (≤ 32%) and total TSNA (≤ 23%) levels in the new product compared to the predicate product over the product storage period
  - Increase (≤ (b) (4) in preservative levels in the new product compared to the predicate product
  - Lower TAMC from the new product compared to the predicate product at each time point during the product storage period
  - Lower TYMC from the new product compared to the predicate product at the beginning (≤ (b) (4) of the product storage period
  - Greater decrease in TAMC from the new product compared to the predicate product over the product storage period
- SE0000091
  - (b) (4) was (b) (4) higher and (b) (4) was (b) (4) lower in the new product compared to the predicate product

    - The HPHCs including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN showed a reduction in these HPHCs between the new and predicate product or minimal increases of no more than 4%
    - Decreases in NNN+NNK (≤ 26%) and total TSNAs (≤ 30%) levels in the new product compared to the predicate product over the product storage period
    - Decrease in product quantity from 37.42 grams to 34.02 grams
- SE0000101
    - The HPHCs including acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN showed a reduction in these HPHCs between the new and predicate product or minimal increases of no more than 4%
    - Increases in NNN+NNK (≤ 36%) and total TSNA (≤ 45%) levels in the new product compared to the predicate product at each time point during the product storage period
    - Decreases in NNN+NNK (≤ 26%) and total TSNAs (≤ 30%) levels in the new product compared to the predicate product over the product storage period
    - Decrease in product quantity from 37.42 grams to 34.02 grams

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant indicated the new products of SE0000088 and SE0000091 had slight changes in tobacco blends, while the tobacco blends for SE0000083, SE0000089, SE0000101 remained unchanged between the new and predicate tobacco products. The applicant provided HPHC quantities for the new and predicate tobacco products of a number of HPHCs including aldehydes, NNN, NNK, nicotine, and benzo[a]pyrene resulting in decreases in HPHCs (up to 50%) and minimal increases in HPHCs (no more than 4%). The applicant also provided information on the stability of the new and predicate products by providing NNN, NNK, mold counts, and yeast counts. This data demonstrated that these stability indicators were not measurably different between the new and predicate 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 as of February 15, 2007).

FDA examined the claim of categorical exclusion from environmental assessment and concluded that categorical exclusion is warranted and no extraordinary circumstances exist which would require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0000083, SE0000088, SE0000089, SE0000091, and SE0000101, as identified on the cover page of this review.