FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0011047, SE0011048, and SE0011050

SE0011047: Granger Select 16 oz.	
Package Type	Foil pouch
Package Quantity	453.6 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]
SE0011048: J.D.'s Blend 16 oz.	
Package Type	Foil pouch
Package Quantity	453.6 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]
SE0011050: Southern Pride 16 oz.	
Package Type	Foil pouch
Package Quantity	453.6 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]
Common Attributes of SE Reports	
Applicant	Swedish Match USA, Inc.
Report Type	Product Quantity Change Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Chewing Tobacco
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] The applicant provided a tobacco cut size of [redacted] (b) , which is equivalent to [redacted] (b) (4)

[2] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Technical Project Lead (TPL):

Colleen K. Rogers -S
2018.12.20 15:09:45 -05'00'

Colleen K. Rogers, 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)

Deirdre L. Kittner -S
Digitally signed by Deirdre L. Kittner -S
Date: 2018.12.27 10:45:11 -05'00'

For 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:

SE0011047: Granger Select 16 oz.	
Product Name	Granger Select 3 oz.
Package Type	Foil pouch
Package Quantity	85.05 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]
SE0011048: J.D.'s Blend 16 oz.	
Product Name	J.D.'s Blend 3 oz.
Package Type	Foil pouch
Package Quantity	85.05 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]
SE0011050: Southern Pride 16 oz.	
Product Name	Southern Pride 3 oz.
Package Type	Foil pouch
Package Quantity	85.05 grams
Tobacco Cut Size	[redacted] (b) (4)
Characterizing Flavor	Natural[2]

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received three Product Quantity Change SE Reports on March 26, 2015, from Swedish Match North America LLC. FDA issued Acknowledgement letters on April 17, 2015. On May 5, 2015, and May 7, 2015, FDA held teleconferences with the applicant requesting additional tobacco product unique identification and revised certification statements. In response to this request, on May 12, 2015, FDA received an amendment (SE0011760) with the tobacco product unique identification information and revised certification statements. On September 7, 2017, FDA received a general correspondence (TC0002691) informing FDA of a name change from Swedish Match North America LLC to Swedish Match USA, Inc. On May 18, 2018, FDA held a teleconference with the applicant requesting tobacco cut size for the new tobacco products. On May 31, 2018, FDA received an amendment (SE0014742) with the requested information for tobacco cut size for the new and predicate tobacco products.

Product Name	SE Report	Amendments
Granger Select 16 oz.	SE0011047	SE0011760 SE0014742
J.D.'s Blend 16 oz.	SE0011048	SE0011760 SE0014742
Southern Pride 16 oz.	SE0011050	SE0011760 SE0014742

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 Idara Udoh on April 17, 2015.

The review concluded that the SE Reports were *not* administratively complete because the following information was not included in the SE Reports:

1. New and predicate tobacco product characterizing flavor

This information was provided during the scientific review process. Therefore, these SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0011047, SE0011048, and SE0011050 were determined to be substantially equivalent by FDA under SE0000083, SE0000088, and SE0000089, respectively. Therefore, the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the new tobacco products are 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 reviews dated August 6, 2015; September 11, 2015; April 30, 2018; and November 29, 2018, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Anh Nguyen on July 31, 2015.

The social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products and that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The new tobacco products have the following difference compared to the corresponding predicate tobacco products: 443% increase in product quantity.

The review identifies the following deficiency that has *not* been adequately resolved:[3]

1. For (b) (4) and SE0011047-50, your new products are being manufactured in a larger package quantity than the predicate products. The package quantity of the new products is greater than that of the predicate products ranging from increases of 200% to 1100%. You provided data to support the claim the changes in package quantity would not lead to different questions of public health. However, there were some concerns with the data that was submitted as address below.

   You provide sales data from the FTC Smokeless Tobacco Report for 2011 as well as SMNA sales data to suggest that consumers prefer moist snuff and chewing tobacco products with smaller package quantities found in the predicate products. You also provide data on SMNA moist snuff products suggesting that the sales data mirror the trends found in the FTC Tobacco Report. However this data is not adequate to resolve this deficiency because of the incomparability of the FTC and SMNA datasets and findings in your data that contradict your argument that consumers prefer products with the smaller package quantity (e.g., annual trends in increasing number of units sold for large package quantity products and annual trends in decreasing number of units sold for small package quantity products); as well as the lack of data on findings on patterns of use (e.g., initiation, frequency of use, or cessation) of the new moist snuff and chewing tobacco product as compared to the predicate products.

   In addition you provided study data for consumer research conducted February 18-23, 2015. This data has limited applicability to the current reports because the study focused on pouch count (e.g., 12 pouches vs. 24 pouches) while the current reports address changes in package quantity; the study focused on snus products while the current reports focus on snuff and chewing tobacco products.

   It is possible that introducing the products in various package quantities may raise different questions of public health. For example, research studies on other consumer products, such as food and beverages, suggest that consumption increases when individuals are presented with a larger package or container quantity. In addition, providing more tobacco in a single package may make it more difficult to quit.

   In order to assess the new products, we need information about how the larger package quantity impacts consumer perceptions, appeal, and use. Submit any information that demonstrates that the package quantity of the new products does not raise different questions of public health. This information may include, but is not limited to:

[3] The social science review evaluated additional SE Reports than those that are the subject of this review.

- Consumer perception studies comparing attitudes, beliefs, and behavioral intentions for the new moist snuff/chewing tobacco products to the predicate products (e.g., studies that ascertain whether larger quantities of smokeless tobacco lead to increased product consumption or product appeal) for individuals
- Market analyses (e.g., sales and/or market segmentation analyses to identify whether increased package quantity has led to increased trends in consumer purchasing or use behavior among current tobacco users or never tobacco users of moist snuff/chewing tobacco products)
- Studies on purchasing frequency that demonstrate that the amount of product used per day or per week is similar between the predicate and new moist snuff/chewing tobacco products
- Other research and analyses conducted to prepare for introduction of the new products into the marketplace

The review concludes that the applicant did not demonstrate that 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 social science perspective. I do not concur with this conclusion. The Office of Science (OS) prepared a memorandum[4] summarizing its current thinking on product quantity changes. With respect to product quantity increases, the currently available scientific evidence examines the effects of product quantity in other consumer products on consumer behavior and perception but is not specific to tobacco products generally or the specific category of tobacco product under social science review. This evidence suggests that changes in product quantity of consumer products may influence consumer behavior but was not specific enough for OS to determine if such changes always lead to changes in behavior, and if not under what condition it would; what threshold (if any) would trigger a change in consumer behavior; what tobacco products would be affected by a quantity change and which would not, and how findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, from a social science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, the differences in product quantity between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health and the social science deficiency should not be conveyed to the applicant.

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

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Dilip Venugopal on May 24, 2018; by Hoshing Chang on June 12, 2018; and by Dilip Venugopal on December 11, 2018.

[4] *See* memorandum on product quantity changes, dated December 7, 2017.

The final environmental review found that the SE Reports did not fully address the environmental effects of manufacturing the new tobacco products, did not provide the first- and fifth-year market projections for the new and predicate tobacco products, and did not discuss whether the applicant is compliant with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from (b) (4) to (b) (4) (443% increase).

The social science review concludes that the applicant did not demonstrate that the differences in product quantity between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. I do not concur with this conclusion. The December 7, 2017, OS memorandum[4] regarding product quantity changes concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0011047, SE0011048, and SE0011050 were previously determined to be substantially equivalent by FDA under SE0000083, SE0000088, and SE0000089, respectively.

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 other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0011047 was previously determined to be substantially equivalent by FDA under SE0000083. Comparison of the new tobacco product to the grandfathered product (Granger Select) reveals that the new tobacco product has the following differences in characteristics from Granger Select, the grandfathered tobacco product:

- 443% increase in product quantity
- Addition of unmodified corn starch
- 26% increase in the complex flavor (b) (4)
- Reduction or minimal increases of no more than 4% of the following HPHCs: acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN
- ≤ 11% increase in NNN+NNK and ≤ 17% increase in total tobacco-specific nitrosamine levels at each timepoint tested during the product storage period[5]

[5] Product storage period was (b) (4). Samples were tested at (b) (4) 2, and (b) (4).

- 16-70% increase in preservative levels at each timepoint tested during the product storage period[5]
- Lower total aerobic microbial counts at each timepoint tested during the product storage period[6]
- 95% decrease in total yeast and mold counts at time zero of the product storage period

The differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000083. Therefore, these differences do not cause the new tobacco product in SE0011047 to raise different questions of public health. Additionally, for the same reasons as discussed above, the difference in product quantity between the new tobacco product in SE0011047 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 SE0011047 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0011048 was previously determined to be substantially equivalent by FDA under SE0000088. Comparison of the new tobacco product to the grandfathered product (J.D.'s Blend) reveals that the new tobacco product has the following differences in characteristics from J.D.'s Blend, the grandfathered tobacco product:

- 443% increase in product quantity
- 17% increase in (b) (4) tobacco
- Reduction or minimal increases of no more than 4% of the following HPHCs: acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN
- 23-27% decrease in NNN+NNK and 19-21% decrease in total tobacco-specific nitrosamine levels at each timepoint tested during the product storage period[5]
- Lower total aerobic microbial counts at each timepoint tested during the product storage period[6]
- Greater decrease in total aerobic microbial counts over the full product storage period (b) (4)
- 73% decrease in total yeast and mold counts at time zero of the product storage period

The differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000088. Therefore, these differences do not cause the new tobacco product in SE0011048 to raise different questions of public health. Additionally, for the same reasons as discussed above, the difference in product quantity between the new tobacco product in SE0011048 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 SE0011048 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0011050 was previously determined to be substantially equivalent by FDA under SE0000089. Comparison of the new tobacco product to the grandfathered

[6] Samples were tested at (b) (4).

product (Southern Pride) reveals that the new tobacco product has the following differences in characteristics from Southern Pride, the grandfathered tobacco product:

- 443% increase in product quantity
- Addition of unmodified corn starch
- 27% increase in the complex flavor (b) (4)
- Reduction or minimal increases of no more than 4% of the following HPHCs: acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN
- ≤ 13% decrease in NNN+NNK and ≤ 6% decrease in total tobacco-specific nitrosamine levels at each timepoint tested during the product storage period[5, 7]
- 38-103% increase in preservative levels at each timepoint tested during the product storage period[5]
- Lower total aerobic microbial counts at each timepoint tested during the product storage period[6]
- Greater decrease in total aerobic microbial counts over the full product storage period (b) (4)
- 97% decrease in total yeast and mold counts at time zero of the product storage period

The differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000089. Therefore, these differences do not cause the new tobacco product in SE0011050 to raise different questions of public health. Additionally, for the same reasons as discussed above, the difference in product quantity between the new tobacco product in SE0011050 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 SE0011050 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act.

FDA examined the environmental effects of finding the new tobacco products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing SE orders.

An Advice/Information Request letter should be issued to the applicant requesting the following information:

1. All of your SE Reports list the manufacturing facility address as 1121 Industrial Drive, Owensboro, KY 42301, while the environmental assessments (EAs) you submitted list Two James Center, 1021 East Cary Street, Suite 1600, Richmond, VA 23219. The address listed in the EA should be the physical location of the manufacturing facility. Clarify the correct physical address of the manufacturing facility.
2. All of your SE Reports lack sufficient information on the environmental effects of manufacturing the new and predicate tobacco products. This information is used to assess the environmental impact of marketing of the new and corresponding predicate tobacco

[7] All timepoints decreased except for the (b) (4) timepoint, which increased 27% (NNN+NNK) or 30% (total TSNAs).

products simultaneously. To evaluate the potential effects of manufacturing, address the following:

a. You stated that there will likely be an increase in product sales due to marketing the new tobacco products. Will there be increased manufacturing due to the new and predicate tobacco products? If so, will that require additional resources for manufacturing waste handling and disposal, such as onsite solid or hazardous waste accumulation capacity or other waste disposal or handling capacity? If so, describe the environmental effects of these increased resources.

b. Will manufacturing the new and predicate tobacco products result in an expansion of the manufacturing facility? If so, identify and evaluate any potential environmental impacts due to the expansion.

c. Will there be new or increased emissions from manufacturing the new and predicate tobacco products? If so, list the compounds and describe the environmental effects of those new or increased emissions.

d. Will manufacturing the new and predicate tobacco products require a revised or new air emissions or wastewater discharge permit?

3. All of your SE Reports lack information that you are in compliance with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). All federal actions are required to comply with ESA and CITES. Therefore, FDA evaluates the potential for violations of ESA and CITES due to its proposed marketing orders. To assess if any adverse effects are anticipated from the proposed action, address the following:

   a. Is any critical habitat affected from the production of the new and predicate tobacco products?

   b. Discuss any adverse effects, if applicable, on species or their habitat identified under ESA and CITES due to (i) the materials used to manufacture the new and predicate tobacco products, (ii) the manufacturing process itself, and (iii) disposal of the new and predicate tobacco products. Provide a statement if there are no anticipated adverse effects.

4. All of your SE Reports lack the current market volumes for the predicate tobacco products and the first- and fifth-year market projections for the new and predicate tobacco products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal from the use of the new tobacco products in conjunction with the predicate tobacco products. If you deem any of this information confidential, mark it as such so that it can be placed in a confidential appendix to the public EA document. Provide the current market volumes for the predicate tobacco products and the market volume projections in the first and fifth year of marketing for the new and predicate tobacco products in Table 1.

TABLE 1: Market Volume Information			
Product	**Current Year Market Volume (pounds)**	**First-Year Projected Market Volume (pounds)**	**Fifth-Year Projected Market Volume (pounds)**
SE0011047			
Predicate to SE0011047			
SE0011048			
Predicate to SE0011048			
SE0011050			
Predicate to SE0011050			

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0011047, SE0011048, and SE0011050, as identified on the cover page of this review.