Technical Project Lead (TPL) Review: SE0012725

SE0012725: J.D.'s Blend 2.5 oz	
Package Type	Foil Pouch
Package Quantity	2.5 oz
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Natural[2]
Attributes of SE Report	
Applicant	Swedish Match USA, Inc.
Report Type	Regular Product Quantity Change
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Chewing Tobacco
Recommendation	
Issue a Substantially Equivalent (SE) order.	

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

Digitally signed by Colleen K. Rogers -S
Date: 2018.09.24 12:59:07 -04'00'

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)

Digitally signed by Matthew R. Holman -S
Date: 2018.09.24 13:47:44 -04'00'

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:

SE0012725: J.D.'s Blend 2.5 oz	
Product Name	J.D.'s Blend 3 oz
Package Type	Foil Pouch
Package Quantity	3 oz
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Natural[2]

The predicate tobacco product is a smokeless loose chewing tobacco product manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the Product Quantity Change SE Report from Swedish Match USA, Inc. on December 14, 2015. FDA issued an Acknowledgement letter on December 18, 2015. FDA issued an Advice/Information Request (A/I) letter on March 11, 2016, to inform the applicant that FDA intends to issue a final decision on this report after completing scientific review of the provisional SE Report (SE0000088) because products that are the subject of provisional SE Reports may not serve as predicate tobacco products under the FD&C Act unless they have been previously found substantially equivalent. FDA issued an A/I letter regarding environmental information requests on May 30, 2018. FDA received a response to the A/I letter on June 26, 2018 (SE0014789).

Product Name	SE Report	Amendments
J.D.'s Blend 2.5 oz	SE0012725	SE0014789

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Cecilia Robinson on December 18, 2015.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0012725 was previously determined to be substantially equivalent by FDA under SE0000088. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated February 23, 2016, and September 4, 2018, conclude 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 discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Rhonda Moore on February 4, 2016.

The social science review concludes that the new tobacco product has different characteristics from the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following difference between the new and predicate tobacco products:

- 16.7% decrease in product quantity

The review concludes that there is currently no available direct scientific evidence on the influence a decrease in tobacco per foil pouch has on consumer perceptions of harm or use intentions. The review also concludes that there is limited relevant scientific literature or scientific evidence from other fields of study (e.g., food science) to indicate that a decrease of this magnitude would cause the new tobacco product to raise different questions of public health from a social science perspective. Therefore, the review concludes that the difference in characteristics between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[3] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity for SE0012725 does not cause the new tobacco product to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary. FDA has determined that the health information 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 tobacco product into interstate commerce.

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

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on May 17, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 24, 2018. The FONSI was supported by an environmental assessment prepared by FDA on September 24, 2018.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a 16.7% decrease in product quantity.

The social science review and OS memorandum[3] conclude that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product for SE0012725 was previously determined to be substantially equivalent by FDA under SE0000088.

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).

Comparison of the new tobacco product in SE0012725 to the grandfathered tobacco product in SE0000088 (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:

- 16.7% decrease in product quantity
- 17% increase in (b) (4)
- Decrease or minimal increase of no more than 4% in the following harmful and potentially harmful constituents: acetaldehyde, arsenic, benzo[a]pyrene, cadmium, crotonaldehyde, formaldehyde, nicotine, NNK, and NNN
- Decrease in NNN+NNK (24-27%) and total TSNAs (19-21%) at each timepoint evaluated during the product storage period[4]
- Decrease in total aerobic microbial counts (b) (4) at each timepoint evaluated during the product storage period[4]
- (b) (4) decrease in total yeast and mold counts at the beginning of the product storage period
- Greater decrease in total aerobic microbial counts over the entire product storage period[5]

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 SE0012725 to

[4] The product storage period (i.e., shelf life) was evaluated over the course of (b) (4).

[5] The entire product storage period is the value at time zero compared to the final timepoint (b) (4).

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 SE0012725 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 SE0012725 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.

FDA examined the environmental effects of finding the 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 SE0012725, as identified on the cover page of this review.