Technical Project Lead (TPL) Review: SE0015215

SE0015215: Red Man Golden Blend (9 oz.)	
Package Type	Foil pouch
Package Quantity	9 ounces
Tobacco Cut Size	[redacted]
Characterizing Flavor	None[2]
Attributes of SE Report	
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) order.	

[1] Cuts per inch

[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: 2019.07.25 12:08:25 -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 Glen D. Jones -S
Date: 2019.07.26 11:36:55 -04'00'

For 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:

SE0015215: Red Man Golden Blend (9 oz.)	
Product Name	Red Man Golden Blend (3 oz.)
Package Type	Foil pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None[2]

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Report on May 2, 2019. FDA issued an acknowledgement letter on May 7, 2019. There are no amendments.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Shireen Fotelargias on May 6, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product was determined to be substantially equivalent by FDA under SE0000085. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed a review 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 review dated July 12, 2019, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and predicate tobacco products are identical except for a change in product quantity. OS prepared a memorandum[3] 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 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, scientific review is unnecessary.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on June 7, 2019.

A finding of no significant impact (FONSI) was signed by Hans Rosenfeldt, Ph.D. for Kimberly Benson, Ph.D. on June 12, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 12, 2019.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 3 ounces to 9 ounces (200% increase).

The OS memorandum[3] concludes 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 was previously determined to be substantially equivalent by FDA under SE0000085.

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 SE0015215 was previously determined to be substantially equivalent by FDA under SE0000085. Comparison of the new tobacco product to the grandfathered

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

product [Red Man Golden Blend (3 oz.)] reveals that the new tobacco product has the following differences in characteristics from Red Man Golden Blend (3 oz.), the grandfathered tobacco product:

- 200% increase in product quantity
- Addition of (b) (4)
- A decrease in all HPHCs tested
- A decrease in NNN (39-40%), NNK (58-67%), and total TSNAs (30-37%) at each time point in the stability study (36 weeks total)

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 SE0000085. Therefore, these differences do not cause the new tobacco product in SE0015215 to raise different questions of public health. Additionally, for the same reasons as discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015215 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 SE0015215 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 this 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 SE0015215, as identified on the cover page of this review.