Technical Project Lead (TPL) Review: SE0013742

SE0013742: Hot Rod Regular King Size 100 Count	
Package Type	Box
Package Quantity	100 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor[1]	None
Attributes	
Applicant	Midwest Tobacco Tube Inc. dba Great Midwest Tube
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[1] 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: 2017.11.24 07:00:56 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2017.11.27 08:18:13 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant certifies that the predicate tobacco product is identical to the new tobacco product except for product quantity. According to the applicant, the predicate tobacco product has the following characteristics:

SE0001497: Hot Rod Regular King Size 200 Count	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	None

The predicate tobacco product is manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 10, 2016, FDA received one Product Quantity Change SE Report from Midwest Tobacco Tube Inc. dba Great Midwest Tube. FDA issued an acknowledgement letter on November 17, 2016. FDA held a teleconference with the applicant on February 9, 2017, and asked for a clarification on the difference in packaging size between the new and predicate tobacco products referenced in the certification statement and for an updated certification statement. The applicant responded with amendment SE0013906, received by FDA on February 15, 2017. FDA issued a Preliminary Finding letter on August 7, 2017. The Preliminary Finding letter identified environmental deficiencies in the applicant's SE Report. The applicant submitted a response (SE0014288), received by FDA on August 29, 2017.

Product Name	SE Report	Amendment
Hot Rod Regular King Size 100 Count	SE0013742	SE0013906 SE0014288

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Lauren DeBerry on November 16, 2016, and August 7, 2017.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0013742 was previously found to be substantially equivalent by FDA under SE0001497. 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 October 3, 2017, concludes that the new tobacco product is 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 Rhonda Moore on December 28, 2016.[2]

The social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product but that 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:

- A decrease in product quantity from 200 tubes to 100 tubes (a 50% difference)

The social science reviewer states that there is currently no available scientific evidence that this change in the number of tubes per box influences consumer use intentions. Further, the reviewer states that evidence from other consumer products suggests that this change in the number of tubes per box would not cause the new tobacco product to raise different questions of public health from a social science perspective.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), smaller product quantities may allow for increased product uptake due to lower barriers to trying the product, are associated with lower product harm perceptions, and reduce product costs or increase product availability, all of which may affect use intentions and behavior, including initiation among youth. However, as explained below, I find that when that evidence is viewed in the context of the evidence provided in this SE Report, as well as other scientific literature and FDA's general experience reviewing SE Reports, and the current state of the evidence, for the type of product at issue here—cigarette tube—a decrease in product quantity would not cause a new tobacco product to raise different questions of public health.

First, based on FDA's experience and knowledge it is very unlikely that youth would initiate tobacco use with the product that is the subject of this SE Report. This is because cigarette tubes require other tobacco products like RYO tobacco filler in order to be assembled into a

[2] An addendum review was completed October 24, 2017, solely to correct SE Report STNs.

finished product that is ready for use. As a result, this requires additional time, effort and expense, which disincentivizes youth from initiating with these types of products. Further, I agree with the social science reviewer that there is currently no available scientific evidence specific to cigarette tubes showing that a decrease in product quantity would influence consumer use intentions.

Second, as described by the social science reviewer, scientific literature suggests that for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), decreasing the product quantity generally would not impact consumer use.[3,4]

Similarly, a decrease in the product quantity of usage-invariant, low convenience, and low salience products also generally would not impact consumer use and behavior, including initiation among youth. A decrease in product quantity for a usage-invariant product generally would not affect initiation because youth generally would not initiate despite a corresponding decrease in price. A decrease in product quantity for a low convenience product also generally would not affect initiation because youth generally would not initiate if product consumption continues to require additional time, preparation and effort to use the product. A decrease in product quantity for a low salience product generally would not affect youth initiation because the product remains not noticeable, easily remembered, or recalled.

There is a high likelihood that cigarette tubes are usage-invariant (since there is no benefit of using a decreased number of cigarette tubes per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space).

Based on the foregoing, as well as FDA's general experience reviewing SE Reports for this type of product, I find that, based on the current state of the evidence, a decrease in product quantity from 200 to 100 cigarette tubes does not cause the new tobacco product to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 10, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 10, 2017.

[3] Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. Journal of Marketing Research, 321-335.

[4] Wansink, B. (1996). Can package size accelerate usage volume? Journal of Marketing, 60, 1-14.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 200 to 100 RYO filtered cigarette tubes.

The social science review concludes that this difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco product meets statutory requirements because it was determined to be substantially equivalent by FDA under SE0001497. When the new tobacco product in SE0013742 is compared to the grandfathered tobacco (GF) product in SE0001497, the only differences is a 50% decrease in package quantity (200 cigarette tubes per box for the GF tobacco product and 100 cigarette tubes per box for the new tobacco product). This is the same difference noted in the comparison of the new tobacco product to the predicate tobacco product that was previously found SE, and the currently available evidence for consumer perception of product quantity changes does not demonstrate that these products raise different questions of public health. Therefore, this difference does not cause the new tobacco product to raise different questions of public health compared to the original grandfathered tobacco product.

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 SE0013742 as identified on the cover page of this review.