

Technical Project Lead (TPL) Review: SE0015635

SE0015635: #208 Apple Flavored	
Package Type	Plastic bag
Package Quantity	1.5 ounces
Characterizing Flavor	Apple ¹
Attributes of SE Report	
Applicant	Sutliff Tobacco Company LLC
Report Type	Product Quantity Change Regular
Product Category	Pipe Tobacco Product
Product Sub-Category	Pipe Tobacco Filler
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: 2020.03.26 15:03:13 -04'00'

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: 2020.03.26 15:06:55 -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:

SE0015635: #208 Apple Flavored	
Product Name	#208 Apple Flavored
Package Type	Plastic bag
Package Quantity	1 pound ²
Characterizing Flavor	Apple ¹

The predicate tobacco product is pipe tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 30, 2019, FDA received a Product Quantity Change SE Report from Sutliff Tobacco Company LLC. On January 16, 2020, FDA issued an Acceptance letter to the applicant. 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

Regulatory reviews were completed by Jessica Kiser on January 16, 2020, and March 25, 2020.

The reviews conclude that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated January 22, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also 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 February 12, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

² One pound is equal to 16 ounces

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 memoranda³ summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, 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 Ronald Edwards on January 27, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 18, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 18, 2020.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 16 ounces to 1.5 ounces (↓91%).

The OS memoranda³ 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 in SE0015635 meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 SE0015635, as identified on the cover page of this review.

³ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.