FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015374 – SE0015375

SE0015374: GAMBLER Gold 1 oz. Mini Bag	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor[1]	None
SE0015375: GAMBLER Menthol 1 oz. Mini Bag	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor[1]	Menthol
Attributes of SE Reports	
Applicant	Top Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Pipe tobacco products
Product Sub-Category	Pipe tobacco filler
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[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: 2019.11.01 13:26:58 -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: 2019.11.01 14:54:23 -04'00'

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:

SE0015374: GAMBLER Gold 1 oz. Mini Bag	
Product Name	Gambler Light Medium Bag (6 oz)
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor[1]	None
SE0015375: GAMBLER Menthol 1 oz. Mini Bag	
Product Name	Gambler Menthol Medium Bag (6 oz)
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor[1]	Menthol

The predicate tobacco products are pipe tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 30, 2019, FDA received two SE Reports (SE0015374 – SE0015375) from Top Tobacco, LP and subsequently issued an acknowledgement letter on August 2, 2019.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Nicholas Hasbrouck on August 2, 2019, and Donna Cheung on October 22, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated August 26, 2019, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review 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 review dated October 8, 2019, concludes 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

Social science reviews were completed by Anh Zarndt on September 9, 2019, and October 15, 2019.

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

- SE0015374: 6 ounces to 1 ounce (83% decrease in product quantity)
- SE0015375: 6 ounces to 1 ounce (83% decrease in product quantity)

The reviews conclude that there is currently no available scientific evidence on the influence that the pipe tobacco filler package quantity has on consumer perceptions of harm or use intentions to indicate that a decrease of this magnitude would cause the new tobacco products 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 corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health from a social science perspective.

The Office of Science (OS) prepared a memorandum[2] summarizing its current thinking on product quantity changes in statutorily regulated tobacco products that, at this time, changes in tobacco product quantity do not cause such new tobacco products to raise different questions of public health. As explained below, the conclusions in the December 7, 2017, memorandum are applicable to the new tobacco products that are the subject of these SE Reports (i.e., pipe tobacco filler, a deemed tobacco product).

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 the effect of reduced price from the effect of decreased size on consumption or initiation. Accordingly, I find that the memorandum's conclusion that, based on the currently available evidence and CTP's experience in reviewing SE Reports, decreases in product quantity for statutory tobacco products do not cause those new tobacco products to raise different questions of public health, also applies to pipe tobacco filler.

[2] *See* memorandum on product quantity changes, dated December 7, 2017. When the memorandum was signed, CTP had yet to receive any Product Quantity Change SE Reports for deemed tobacco products.

Based on the foregoing, I find that, based on the current state of the evidence, an 83% decrease in product quantity of pipe tobacco filler in SE0015374 and SE0015375 does not cause the new tobacco products in these SE Reports to raise different questions of public health. Therefore, 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.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on August 15, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 11, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 11, 2019.

6. CONCLUSION AND RECOMMENDATION

The tobacco product characteristics of the new and corresponding predicate tobacco products are identical except for an 83% decrease in product quantity (6 ounces to 1 ounce).

The social science review and the finalized memorandum[2] conclude that based on OS's experience and the currently available evidence, the decrease in product quantity in SE0015374 and SE0015375 does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0015374 and SE0015375 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0015374 – SE0015375, as identified on the cover page of this review.