FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015369-SE0015371

SE0015369: HIGH CARD Gold 5 oz. Medium Bag	
Package Type	Bag
Package Quantity	5 ounces
Characterizing Flavor[1]	None
SE0015370: LARGO Menthol 0.75 oz. Pouch	
Package Type	Pouch
Package Quantity	0.75 ounces
Characterizing Flavor[1]	Menthol
SE0015371: GAMBLER Regular 1 oz. Mini Bag	
Package Type	Bag
Package Quantity	1 ounce
Characterizing Flavor[1]	None
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):

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Date: 2019.11.01 13:26:30 -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 14:52:56 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015369: HIGH CARD Gold 5 oz. Medium Bag	
Product Name	Gambler Light Medium Bag (6 oz)
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor[1]	None
SE0015370: LARGO Menthol 0.75 oz. Pouch	
Product Name	Gambler Menthol Pouch (0.65 oz)
Package Type	Pouch
Package Quantity	0.65 ounces
Characterizing Flavor[1]	Menthol
SE0015371: GAMBLER Regular 1 oz. Mini Bag	
Product Name	Gambler Regular Medium Bag (6 oz)
Package Type	Bag
Package Quantity	6 ounces
Characterizing Flavor[1]	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 26, 2019, FDA received three SE Reports (SE0015369 - SE0015371) from Top Tobacco, LP and subsequently issued an acknowledgement letter on August 1, 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 1, 2019, and Donna Cheung on October 21, 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 6, 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 18, 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 between the new and corresponding predicate tobacco products:

- SE0015369: 6 ounces to 5 ounces (17% decrease in product quantity)
- SE0015370: 0.65 ounces to 0.75 ounces (15% increase in product quantity)
- SE0015371: 6 ounces to 1 ounce (83% decrease in product quantity)

The review concludes 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 an increase or decrease of these magnitudes 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).

[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.

With respect to product quantity increases, as explained in the memorandum for statutorily-regulated tobacco products, the currently available scientific evidence examines the effects of product quantity on behavior and perception in other consumer products and is not specific to tobacco products. There is inadequate information to determine how findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior and, relatedly, what threshold (if any) would trigger a change in consumer behavior. There is similarly no currently available evidence specific to pipe tobacco filler or other information to determine how the findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior for pipe tobacco filler and, relatedly, what threshold (if any) would trigger a change in consumer behavior. Accordingly, I find that the memorandum's conclusion that, based on the currently available evidence and CTP's experience in reviewing SE Reports, increases 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. 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.

Based on the foregoing, I find that, based on the current state of the evidence, a 15% increase or 17% or 83% decrease in product quantity of pipe tobacco filler in SE0015370, SE0015369, and SE0015371, respectively, 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 Susana Addo Ntim on August 21, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 9, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 9, 2019.

6. CONCLUSION AND RECOMMENDATION

The tobacco product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

- SE0015369: 6 ounces to 5 ounces (17% decrease)
- SE0015370: 0.65 ounces to 0.75 ounces (15% increase)
- SE0015371: 6 ounces to 1 ounce (83% decrease)

The social science review and the finalized memorandum[2] conclude that based on OS's experience and the currently available evidence, the increase and decrease in product quantity in SE0015370,

SE0015369, and SE0015371, respectively, does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0015369 – SE0015371 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 SE0015369 – SE0015371, as identified on the cover page of this review.