FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014918

SE0014918: Black & Mild Shorts	
Package Type	Box
Package Quantity	5 cigars
Length	88.9 mm
Diameter	9.62 mm
Characterizing Flavor	None[1]
Additional Properties	Plastic tip
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular Product Quantity Change
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped
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: 2019.01.29 09:20:15 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science

Signatory Decision:

X 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)

Matthew R. Holman -S

Digitally signed by Matthew R. Holman -S
Date: 2019.01.29 09:36:31 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0014918: Black & Mild Shorts	
Product Name	Black & Mild Fast Break Cigar
Package Type	Box
Package Quantity	6 cigars
Length	88.9 mm
Diameter	9.62 mm
Characterizing Flavor	None[1]
Additional Properties	Plastic tip

The predicate tobacco product is an unfiltered, sheet-wrapped cigar manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one Product Quantity Change Substantial Equivalence (SE) Report on November 2, 2018, from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter on November 8, 2018. On December 4, 2018, FDA received an unsolicited amendment (SE0015003) to amend the Environmental Assessment.

Product Name	SE Report	Amendments
Black & Mild Shorts	SE0014918	SE0015003

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 Shireen Fotelargias on November 8, 2018, and by Nicholas Hasbrouck on January 25, 2019.

The final review concludes 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 December 4, 2018, 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 January 24, 2019, 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 Anh Zarndt on December 14, 2018.

The social science review concludes that the new tobacco product has different characteristics from the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The new tobacco product has the following difference compared to the predicate tobacco product:

- 17% decrease in package quantity

The applicant provided data from Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study in support of the change from 6 cigars per package in the predicate tobacco product to 5 cigars per package in the new tobacco product. The data focused on the number of cigars (cigarillos) smoked per day, among adult respondents who reported using cigarillos "every day" or "some days" in the past 30 days. The descriptive data provided by the applicant show that a large proportion of past 30-day adult users use 0 to 5 cigarillos a day. Similarly, the applicant presents data for current established cigarillo users, concluding that most use fewer than 5 cigarillos per day on the days they smoke cigarillos. The applicant states that the new tobacco product count of five cigars per package more closely aligns with current use patterns than does the predicate tobacco product and, therefore, they do not expect that such a change would affect use behavior.

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. The social science review relied on this memorandum in determining that the difference in product quantity between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health. As explained below, I agree with the social science reviewer that the conclusions in the December 7, 2017, memorandum are applicable to the new tobacco product that is the subject of this SE Report (i.e., a cigar).

[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 in other consumer products on behavior and perception 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 cigars 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 cigars 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 do not cause new tobacco products to raise different questions of public health applies to cigars.

With respect to product quantity decreases, like with statutorily-regulated tobacco products, although there is some evidence that is specific to cigars, those studies do not separate out the effect of reduced price from size on consumption or initiation.[3] Similarly, other cigar-specific evidence does not separate out the effect of characterizing flavor on consumption or initiation.[4] Accordingly, I find that consistent with the memorandum's conclusion, based on the currently available evidence and CTP's experience in reviewing SE Reports, decreases in product quantity of cigars do not cause such new tobacco products to raise different questions of public health.

Based on the foregoing, as well as FDA's general experience, I find that, based on the current state of the evidence, a 17% decrease in product quantity of cigars does not cause the new tobacco product in this SE Report to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Ronald Edwards on January 28, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 29, 2019. The FONSI was supported by an environmental assessment prepared by FDA on January 29, 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 6 to 5 cigars per package (17% decrease).

[3] Delnevo CD, Giovenco DP, Miller Lo EJ. Changes in the mass-merchandise cigar market since the Tobacco Control Act. *Tob Regul Sci.* 2017; 3(2 suppl 1):S8-S16.

[4] Delnevo CD, Giovenco DP, Ambrose BK, Corey CG, Conway KP. Preference for flavoured cigar brands among youth, young adults and adults in the USA. *Tob Control* 2015; 24(4):389-94.

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

The predicate tobacco product 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 SE0014918, as identified on the cover page of this review.