FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014625

SE0014625: Black & Mild FT - 5 Pack	
Package Type	Hard Pack
Package Quantity	5 cigars
Length	110 mm
Diameter	8.9 mm
Ventilation	None
Characterizing Flavor	None[1]
Additional Properties	Filter tip
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular Product Quantity Change
Product Category	Cigars
Product Sub-Category	Filtered, 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: 2018.07.12 13:47:07 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product 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: 2018.07.12 13:53:50 -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:

SE0014625: Black & Mild FT - 5 Pack	
Product Name	Black & Mild FT - 7 Pack
Package Type	Hard Pack
Package Quantity	7 cigars
Length	110 mm
Diameter	8.9 mm
Ventilation	None
Characterizing Flavor	None[1]
Additional Properties	Filter tip

The predicate tobacco product is a filtered, sheet-wrapped cigar manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one Product Quantity Change SE Report on April 13, 2018, from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter on April 20, 2018. On June 1, 2018, FDA conducted a telecon to request ventilation information for unique identification of the new and predicate tobacco products. On June 5, 2018, FDA received an amendment (SE0014750) containing the requested ventilation information.

Product Name	SE Report	Amendments
Black & Mild FT - 5 Pack	SE0014625	SE0014750

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Keyur Patel on April 20, 2018.

The 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 May 15, 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 July 12, 2018, 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 David Portnoy on April 20, 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:

- 29% 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 seven cigars per package in the predicate tobacco product to five 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 thirty days. The applicant states that the data show less than half of such respondents smoke cigarillos less than weekly (defined as less than 0-4 days per week) and among that group, only approximately six percent reported smoking more than five cigarillos per day on the days they smoke cigarillos. Similarly, the applicant presents data for current established cigarillo users, concluding that most use fewer than five 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,

[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.

memorandum are applicable to the new tobacco product that is the subject of this SE Report (i.e., a cigar).

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 29% 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 William Brenner on June 26, 2018.

The environmental review found the applicant did not provide (1) the marketing status of the predicate tobacco product and (2) the (b) (4) filter weight and length for the new tobacco product. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

[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.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 7 to 5 cigars per package (29% decrease).

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 the new tobacco product substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Advice/Information Request letter should be issued to the applicant requesting the following information:

1. Your SE Report does not provide the current marketing status of the predicate product. The status of the predicate product allows the Agency to fully assess the environmental impacts of the proposed action of issuing a marketing order for the new product.
    a. Clarify whether the predicate product is currently on the market.
    b. If the predicate product is currently marketed, provide the current-year market volume in number of cigars and in metric tons in Table 1.

Table 1: Predicate Product Market Volume		
STN	Current-Year Predicate Product Market Volume (# of cigars)	Current-Year Predicate Product Market Volume (Metric Tons)
GF1602172		

2. Your SE Report lacks the (b) (4) filter weight and length for the new product. This information allows for an accurate assessment of the cigar butt waste generated from disposal of the new product. Provide the cigar filter weight (grams) and length (millimeters) for the new product in the Table 2.

Table 2: Cigar Butt Information		
STN	Weight of cigar filter (grams)	Length of cigar filter (millimeters)
SE0014625		

If the applicant adequately responds to the request and an EIS or FONSI is completed, an SE order letter should be issued for the new tobacco product in SE0014625, as identified on the cover page of this review.