FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0002733

SE0002733: Montclair Blue King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.85 mm
Ventilation	14%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Commonwealth Brands, Inc.
Report Type	Provisional
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Todd L. Cecil -S
Date: 2021.05.20 08:44:45 -04'00'

Todd Cecil, Ph.D.
Associate 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: 2021.05.24 09:56:09 -04'00'

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:

SE0002733: Montclair Blue King Box	
Product Name	Montclair Full Flavor Kings Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.85 mm
Ventilation	12%
Characterizing Flavor	None

The predicate tobacco product is a combusted filtered cigarette manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Report on March 18, 2011. On April 6, 2011, FDA received a resubmitted SE Report because the original submission was password protected (TC0000093). FDA issued an Acknowledgement letter on August 26, 2011. FDA issued an Advice/Information Request (A/I) letter on January 22, 2013. On February 21, 2013, FDA received the applicant's response to the A/I letter (SE007400). On March 11, 2015, FDA issued a Notification letter, indicating that scientific review would begin on April 25, 2015. FDA issued a Preliminary Finding (PFind) letter on May 7, 2015. On June 5, 2015, FDA received the applicant's response to the PFind letter (SE0011967). FDA issued an Advice/Information Request letter on October 5, 2015. On December 3, 2015 and December 4, 2015, FDA received the applicant's response to the A/I letter (SE0012708 and SE0012709). FDA issued a Preliminary Finding letter on March 9, 2016. On April 8, 2016, FDA received the applicant's response to the PFind letter (SE0013296). On May 4, 2016, FDA received an amendment in response to FDA's request for English translation for part of the April 8, 2016, amendment (SE0013347). FDA issued an NSE order letter on January 4, 2018. On January 10, 2018, FDA received a meeting request (TC0003414). FDA issued a "Meeting Denied" letter on February 2, 2018. On March 9, 2018, FDA received a Request for Consolidated Supervisory Review (AP0000043). Following review of this request, FDA issued a Rescission of Not Substantially Equivalent Order (Rescission) letter rescinding the NSE order for SE0002733 on April 17, 2019. In addition to the Rescission letter, FDA issued an Appeal Granted letter for AP0000043 directing the applicant to submit information about the single ingredient components of a complex black ink ingredient found in the new product on April 17, 2019. On July 12, 2019, FDA received the applicant's response to the Appeal Granted letter (AP0000060).

New Tobacco Product Name	SE Report	Amendments
Montclair Blue King Box	SE0002733	SE0007400
		SE0011967
		SE0012708
		SE0012709
		SE0013296
		SE0013347
		AP0000060

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 Stephanie Durkin on January 22, 2013, and by Laila Noory on May 30, 2014.

The final review concludes that this 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 other than exclusively in test markets as of February 15, 2007). The OCE review dated July 17, 2015, 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. [1]

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Shixia Feng on August 26, 2015, January 19, 2016, and May 27, 2016, and Lida Oum on August 16, 2019.

The final chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product and that the SE Report lacks adequate evidence to demonstrate that the differences do not cause the new tobacco

[1] An addendum review was completed on August 21, 2019, to clarify that the characterizing flavor of the predicate tobacco product is "none." The addendum review does not change the conclusion of the initial grandfather determination dated July 17, 2015.

product to raise different questions of public health. The review identifies the following deficiency that has *not* been adequately resolved:

1. Your SE Report provided HPHC data in mainstream smoke measured under both non-intense and intense smoking regimens for the surrogate new product but not for the predicate product. In order for us to assess the changes in HPHC yield in the new product, mainstream smoke data for the predicate product was needed for comparison. Without this information, we cannot determine that the addition of (b)(4) and (b)(4) in the monogram ink of the new product does not raise different questions of public health. FDA needed mainstream smoke yields of the following HPHCs in the predicate product:

    - Benzene, styrene, isoprene, and toluene

    If your predicate product had not been available for testing, there were options which you may have chosen to demonstrate substantial equivalence. Below are some options, though other alternative options may have been acceptable. For example, the predicate product could have been manufactured at present day consistent with the product composition and design specifications in place at the time the grandfathered predicate product was originally manufactured. Another option would have been to submit mainstream smoke HPHC data for product other than the predicate product (referred to as surrogate tobacco product) that could have been extrapolated to the predicate product. Without this information, FDA cannot find that the changes to the new tobacco product do not raise different questions of public health from a chemistry perspective.

The final chemistry review concludes that the new product has different characteristics compared to the predicate product, and the differences may cause the new product to raise different questions of public health from a chemistry perspective. For this SE Report, the new product contains fire standard compliant (FSC) cigarette paper, while the predicate product contains non-FSC cigarette paper. The applicant provided TNCO data and the results did not show meaningful increases in the new product compared to the predicate product. In addition, the new product contains (b)(4) the monogram ink of the new product but not in the predicate product. Although the quantities of both ingredients are small relative to the total cigarette weight (0.00006% and 0.00035% per cig), the results from the Smith *et. al.* ***Error! Bookmark not defined.*** study may raise toxicological concerns due to the potential increase in benzene, styrene, and toluene in the new product compared to the predicate product. The applicant provided mainstream HPHC smoke yields (benzene, styrene, and toluene) for the surrogate new product but not for the predicate product. In order to assess the HPHC exposure in the new product, mainstream HPHC smoke data for benzene, styrene, and toluene in the predicate product is needed for comparison to determine if the addition of (b)(4) in the new product does not raise different questions of public health.

Therefore, the review concludes that the applicant did not demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. TOXICOLOGY

Toxicology reviews were completed by Arianne Motter on January 28, 2016, and June 3, 2016 and Jueichuan (Connie) Kang on August 30, 2019.

The final toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition of pigment red (b)(4) /cigarette) and (b)(4) µg/cigarette) in the monogram ink

The applicant submitted references and scientific rationales stating that small increases in (b)(4) and the additions of (b)(4) (b)(4), have minimal impacts on smoke chemistry. These combinations of ingredients have unknown toxicity upon inhalation, and their pyrolysis products are not well understood. The applicant submitted HPHC data for the surrogate new product, including benzene, styrene, and toluene, based on the Smith et al., 2013 study demonstrating that (b)(4) increases the smoke yields for these HPHCs, but not for the predicate product. However, the total tobacco weight is decreased in the surrogate new product from (b)(4) to (b)(4) /cig, representing a total (b)(4) g/cig (1.8%) decrease compared to the predicate product. Given that tobacco itself is the largest contributor of VOCs[2] in the mainstream smoke yields, such as benzene, styrene, isoprene, and toluene, it is unlikely that the relatively small additions/increases of the monogram ink ingredients will have significant impacts on the smoke yields of the HPHCs.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of an SE order under section 910(a) of the FD&C Act for this provisional SE Report (SE0002733) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco product:

- Decrease in cigarette mass -1.8%

[2] Note that the toxicologist incorrectly indicates that benzene, styrene, isoprene, and toluene were members of the polyaromatic hydrocarbon (PAH) classification, when they should be identified as members of the volatile organic compound (VOC) classification.

- Addition of (b)(4) µg/cigarette) and (b)(4) µg/cigarette) in the monogram ink

The final social science review concludes that the differences in cigarette mass between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. The final chemistry review concludes that the applicant added two pigments to the monogram ink, which was printed in the combusted portion of the cigarette in the new tobacco product and was not present in the predicate tobacco product. The addition of these pigments to the combusted portion of the tobacco product could result in an increase in certain HPHCs (benzene, styrene, isoprene, and toluene). The applicant provided the smoke yields of these HPHCs for the new tobacco product and the surrogate new tobacco product but did not provide this information for the predicate tobacco product. However, the final toxicology review indicated that the VOCs (benzene, styrene, isoprene, and toluene) contributed by the pigments would be smaller than the reduction in VOCs resulting from the decrease in tobacco mass. A reduction in the VOCs in the tobacco smoke would not cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health.

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

In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

Because the proposed action is issuing an SE order for this provisional SE Report, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

An SE order letter should be issued for the new tobacco product in SE0002733, as identified on the cover page of this review.