FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015095

SE0015095: Marlboro 72's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Attributes of SE Report	
Applicant	Philip Morris USA
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.05.17 16:14:22 -04'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
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: 2019.05.20 07:02:19 -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:

SE0015095: Marlboro 72's Box	
Product Name	Marlboro 72's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.89 mm
Ventilation	15%
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 an SE Report from Philip Morris USA Inc. on February 26, 2019. FDA issued an Acknowledgement letter on March 4, 2019. No amendments were received.

Product Name	SE Report
Marlboro 72's Box	SE0015095

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 Ryan Nguy on March 4, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015095 was determined to be substantially equivalent by FDA under SE0013979. Therefore, this tobacco product 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 May 10, 2019, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

A chemistry review was completed by Andrew Idzior on April 18, 2019.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry 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 (b) (4) and (b) (4); Increases in (b) (4) (68%), (b) (4) (68%), and (b) (4) (225%) to the cigarette paper
- Increases of (b) (4) (20%) (b) (4) (250%), (b) (4) (174%), (b) (4) (30%), and (b) (4) (98%) in the filter
- Addition of (b) (4) to the plug wrap

The new product has ingredient changes in the cigarette paper, filter, and plug wrap compared to the predicate product. These differences could increase tar, nicotine, carbon monoxide (TNCO) and harmful and potentially harmful constituent (HPHC) yields such as acetaldehyde, crotonaldehyde, acrolein, formaldehyde, and benzo[α]pyrene. Additionally, the engineering review identified design differences od 8% higher cigarette paper band width and a decrease in filter total denier. These engineering differences could affect TNCO and benzo[α]pyrene smoke yields. However, the submitted ISO and CI machine-smoking regimen HPHC and TNCO data for the new product were analytically equivalent to the data submitted for the predicate product.

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 chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Jimin Kim on April 17, 2019.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- 125% increase in cigarette paper band porosity
- 8.3% decrease in cigarette paper band width
- 5% decrease in total denier

The applicant provided test data for cigarette paper band porosity for the new tobacco products, which is within the range limits for the predicate tobacco products. As a result, the manufacturing of the new tobacco product is well-controlled and the difference in cigarette

paper band porosity between the new and predicate tobacco products does not cause a concern.

The 8% decrease in cigarette paper band width will impact the overall air flow into the cigarette and TNCO yields. Similarly, the 6% decrease in filter total denier will affect filter efficiency, and thus impact TNCO and benzo[α]pyrene yields. The effects of the design changes on cigarette paper band width and filter total denier on smoke constituent yields were deferred to the chemistry review. As summarized for the chemistry review, the submitted ISO and CI machine-smoking regimen HPHC and TNCO data for the new product were analytically equivalent to the data submitted for the predicate product. Accordingly, the decreases in the cigarette paper band width and filter total denier do not cause concerns in the new tobacco product.

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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Kristen Wurcel on April 22, 2019.The 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:

- Cigarette paper
  - 24% increase in (b) (4)
  - 225% increase (b) (4)
  - Addition of (b) (4)
  - 68% increases in (b) (4) and (b) (4)
- Tipping Adhesive, Filter Tow, and Plug Wrap
  - Addition of (b) (4)
- Filter Tow
  - 1% increase in (b) (4)
  - 250% increase in (b) (4)
  - 174% increase in (b) (4)
  - 30% increase in (b) (4)
  - 98% increase in (b) (4)
- Plug Wrap
  - Addition of (b) (4)

The increases in (b) (4), (b) (4), and (b) (4) can present a toxicological concern because their pyrolysis products can lead to increases in smoke yields of certain HPHCs as described in the chemistry review. The toxicology review references the chemistry review that the smoke yields of TNCO and other relevant HPHCs are not analytically important and concludes that these cigarette paper ingredient differences do not cause a concern. The toxicology review also determines that the increases in (b) (4) and (b) (4) to the cigarette paper will increase the burn rate and lower puff count. This is consistent with the

HPHC data provided by the applicant. As a result, the toxicology review does not have concern with the increases in these burn rate modifiers. Since the tipping adhesive, filter tow, and plug wrap ingredients are not expected to be burned or otherwise volatilized during typical product use, consumer exposure to ingredients in these components is expected to be minimal and the associated ingredient changes do not cause a toxicological concern.

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 toxicology perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 7, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 7, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Cigarette paper
  - 24% increase in (b) (4)
  - 225% increase (b) (4)
  - Addition of (b) (4)
  - 68% increases in (b) (4) and (b) (4)
- Tipping Adhesive
  - Addition of (b) (4)
- Filter Tow
  - 1% increase in (b) (4)
  - 250% increase in (b) (4)
  - 174% increase in (b) (4)
  - 30% increase in (b) (4)
  - 98% increase in (b) (4)
- Plug Wrap
  - Addition of (b) (4)
- 125% increase in cigarette paper band porosity
- 8.3% decrease in cigarette paper band width
- 5% decrease in total denier

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The ingredient and design changes to the cigarette paper and filter could affect TNCO and other HPHC smoke yields such as acetaldehyde, crotonaldehyde, acrolein, formaldehyde, and benzo[α]pyrene. The submitted ISO and CI machine-smoking regimen HPHC and TNCO data for the new product were analytically equivalent to the data submitted for the predicate product. Because there are no analytically important HPHC differences of the new tobacco product in comparison to the predicate tobacco product, the ingredient and design changes are not a concern. Therefore, the differences in characteristics between the new

and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0013979.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015095 was previously determined to be substantially equivalent by FDA under SE0013979. Comparison of the new tobacco product to the grandfathered product (Marlboro Seventy-Twos Box) in SE0013979 reveals that the new tobacco product has the following differences in characteristics from Marlboro Seventy-Twos Box, the grandfathered tobacco product:

- 36% increase of (b) (4) – (b) (4))
- 7% decrease in (b) (4) in the tobacco blend
- Addition of (b) (4) , (b) (4) , (b) (4) , and (b) (4)
- Increases in (b) (4) (5%), (b) (4) (98%), (b) (4) (108%), and (b) (4) (b) (4) (594%) in the cigarette paper
- Addition of (b) (4) in the tipping paper
- Addition of (b) (4) to the tipping adhesive

The differences in characteristics listed above, other than the differences in the additions and increases in cigarette paper, tipping paper, and tipping adhesive ingredients, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE00013979. Therefore, these differences do not cause the new tobacco product in SE0015095 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in added (b) (4) , (b) (4) , (b) (4) , (b) (4) , (b) (4) (b) (4) , and (b) (4) , together with the increase in (b) (4) , (b) (4) , (b) (4) , and (b) (4) between the new tobacco product in SE0015095 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. The TNCO and acetaldehyde, acrolein, formaldehyde, and benzene ISO and CI smoke yields of the new tobacco product are analytically equivalent to the grandfathered tobacco product. Therefore, whether comparing the new tobacco product in SE0015095 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products 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.

FDA examined the environmental effects of finding the 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 SE0015095, as identified on the cover page of this review.