Technical Project Lead (TPL) Review: SE0015044 and SE0015074

SE0015044: Eclipse Menthol	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	24%
Characterizing Flavor	Menthol
Source of Energy	Carbon heat source
SE0015074: Eclipse	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	24%
Characterizing Flavor	None
Source of Energy	Carbon heat source
Attributes of SE Reports	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Non-combusted, non-filtered[1]
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] The applicant stated that the new and corresponding predicate tobacco products are non-combusted, filtered cigarettes. However, the applicant also stated that the filter tips do not function as mainstream smoke filters per se but are hollow tubes composed of cellulose acetate and serve as a mouthpiece for the user and lessen the chance of any tobacco entering the mouth. Based on this information, and in the absence of pressure drop, FDA has determined that the new and predicate tobacco products are non-combusted, non-filtered cigarettes.

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2019.11.13 09:26:12 -05'00'

Charles Feng, 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)

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Date: 2019.11.13 16:43:17 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015044: Eclipse Menthol	
Product Name	Eclipse Menthol
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	24%
Characterizing Flavor	Menthol
Source of Energy	Carbon heat source
SE0015074: Eclipse	
Product Name	Eclipse
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	24%
Characterizing Flavor	None
Source of Energy	Carbon heat source

The predicate tobacco products are non-combusted, non-filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Reports on January 4, 2019 (SE0015044), and January 31, 2019 (SE0015074). FDA issued Acknowledgement letters on January 10, 2019 (SE0015044), and February 5, 2019 (SE0015074). FDA issued Advice/Information (A/I) Request letters on March 1, 2019 (SE0015044), and March 28, 2019 (SE0015074). On August 20, 2019, FDA received the applicant's response to the A/I Request letters (SE0015407).

Product Name	SE Report	Amendments
Eclipse Menthol	SE0015044	SE0015407
Eclipse	SE0015074	

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 Sarah Amyot on January 10, 2019 (SE0015044), and Crystal Caesar on February 5, 2019 (SE0015074). The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015044 and SE0015074 were determined to be substantially equivalent by FDA under SE0006178 and SE0006177, respectively. Therefore, the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) 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 section910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated October 8, 2019, concludes that the new tobacco products are 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

Chemistry reviews were completed by Margret Schmierer on February 22, 2019 and March 18, 2019, and Scott Wasdo on October 3, 2019.

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

- 45% (or (b)(4) mg/cigarette) (b) (4) in (b) (4)

The higher amount of (b)(4) in the (b)(4) (b) (4) may increase carbonyls and PAHs yields due to pyrolysis. However, the applicant provided aerosol measurements for tar and HPHCs (acetaldehyde, acrolein, formaldehyde, B[a]P, nicotine and CO) under ISO and CI smoking regimens, and validation data for the test methods used. The data indicate that the aerosol yields of all HPHCs in the new products are equivalent to or lower than the corresponding aerosol yields in the predicate products.

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 chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Michael Morschauser on February 22, 2019, March 19, 2019, and September 27, 2019.

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

- 13% decrease in (b) (4) in (b) (4)

The (b) (4) is used as (b)(4) for the heat source. However, the new tobacco products contain alternate (b) (4) materials resulting a 13% decrease in (b)(4) . The applicant provided temperature data from two locations along the tobacco rod during puffing for 20 puffs. The temperature for the new tobacco products was similar or lower than that for the corresponding predicate tobacco products, which is not expected to negatively impact the aerosol HPHC yields.

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 and engineering perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 5, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 5, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 45% (or (b)(4) mg/cigarette) increase in (b)(4) in (b) (4)
- 13% decrease in (b) (4) in (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The higher amount of (b)(4) in the (b)(4) (b) (4) around the heat source could affect the aerosol HPHCs yields, including PAHs and carbonyls. However, the (b) (4) of the (b) (4) decreased and the measured temperature along the tobacco rod was either similar or lower as compared to the corresponding predicate tobacco products. These changes are not expected to negatively impact the aerosol HPHC yields. This is confirmed by the aerosol yields for tar, nicotine, CO, acetaldehyde, acrolein, formaldehyde, and B[a]P in the new tobacco products under both ISO and CI regimens, which are analytically equivalent to or lower than those in the predicate tobacco products.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0006178 and SE0006177.

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 products in SE0015044 and SE0015074 were previously determined to be substantially equivalent by FDA under SE0006178 and SE0006177, respectively. Comparison of the new tobacco products to the grandfathered products (Eclipse Menthol in SE0006178 and Eclipse in GF1300880) reveals that the new tobacco products have the following differences in characteristics from Eclipse Menthol and Eclipse, the grandfathered tobacco products:

- 45% (or (b)(4) mg/cigarette) increase in (b)(4) in (b) (4)
- 13% decrease in (b) (4) in (b) (4)
- 14% increase in (b)(4) cigarette paper base paper porosity

The differences in characteristics listed above, other than the differences in (b) (4), are the same difference in characteristics identified for the new and grandfathered tobacco products in SE0006178 and SE0006177. Therefore, these differences do not cause the new tobacco products in SE0015044 and SE0015074 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in (b) (4) between the new tobacco products in SE0015044 and SE0015074 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015044 and SE0015074 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

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 SE0015044 and SE0015074, as identified on the cover page of this review.