

**Technical Project Lead (TPL) Review: SE0015804**

| SE0015804: Newport Non-Menthol Box           |                               |
|--|-------------------------------|
| Package Type                                 | Box                           |
| Package Quantity                             | 20 cigarettes                 |
| Length                                       | 80 mm                         |
| Diameter                                     | 7.9 mm                        |
| Ventilation                                  | 0%                            |
| Characterizing Flavor                        | None                          |
| Attributes of SE Report                      |                               |
| Applicant                                    | R.J. Reynolds Tobacco Company |
| 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 Gloria J. Kulesa -S  
Date: 2020.07.13 10:46:44 -04'00'

Gloria Kulesa  
Engineering 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: 2020.07.13 11:34:57 -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:

| SE0015804: Newport Non-Menthol Box |                     |
|------------------------------------|---------------------|
| Product Name                       | Newport Menthol Box |
| Package Type                       | Box                 |
| Package Quantity                   | 20 cigarettes       |
| Length                             | 80 mm               |
| Diameter                           | 7.9 mm              |
| Ventilation                        | 0%                  |
| Characterizing Flavor              | Menthol             |

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 3, 2020, FDA received an SE Report (SE0015804) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued the applicant an Acceptance letter for this SE Report on April 8, 2020.

### 1.3. SCOPE OF REVIEW

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

## 2. REGULATORY REVIEW

An Acceptance review was completed by Fatima Sow on April 8, 2020. The 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated April 25, 2020, 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 reviews dated June 11, 2020 and July 10, 2020, conclude 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 Samantha Reilly on May 15, 2020.

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 fire standards compliant (FSC) cigarette paper
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- 0.4% increase in (b) (4)
- 15% increase in carbon monoxide (CO) on the ISO smoking regimen

The new tobacco product is a non-mentholated combusted cigarette while the predicate tobacco product is a mentholated combusted cigarette. The new tobacco product contains differences in the ingredients added to tobacco compared to the predicate tobacco product. The absence of (b) (4) and the lower quantities of (b) (4) and (b) (4) do not significantly impact harmful and potentially harmful constituents (HPHC) yields. However, as (b) (4) has toxicological implications, the higher quantity of (b) (4) in the new tobacco product has been deferred to toxicology to determine if the new tobacco product raises different questions of public health. The new tobacco product contains fire-standards compliant (FSC) cigarette paper while the predicate tobacco product contains non-FSC cigarette paper. Because of the different cigarette papers, the new tobacco product contains (b) (4) and (b) (4) that are not present in the predicate tobacco product. In addition, the new tobacco product uses a higher quantity of combustion modifiers and has a higher base paper porosity compared to the predicate tobacco product. These differences may alter the relative smoke chemistry of the new and predicate tobacco products. The applicant provided tar, nicotine, and carbon monoxide (TNCO), acetaldehyde, acrolein, formaldehyde, B[a]P, and benzene yields for the new and predicate tobacco products measured under ISO and CI smoking regimens. The tar, nicotine, acetaldehyde, acrolein, formaldehyde, B[a]P, and benzene yields in mainstream cigarette smoke are analytically equivalent between the new and predicate tobacco products or not analytically equivalent and lower in the new tobacco product and therefore, do not raise different questions of public health. However, the CO yields under the ISO smoking regimen are not analytically equivalent and higher from the new tobacco product. Thus, the CO yields under the ISO smoking regimen are deferred to toxicology to determine if the CO yield from the new tobacco product raises different questions of public health.

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 chemistry perspective.

#### **4.2. ENGINEERING**

An engineering review was completed by James Melchiors on May 20, 2020.

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:

- Addition of FSC cigarette paper
- 6% increase in cigarette paper base paper porosity
- 25% increase in filter total denier
- 10% decrease in denier per filament
- 10% increase in filter density
- 34% increase in filter pressure drop

The changes in the cigarette paper base paper porosity, filter total denier, denier per filament, filter density, and filter pressure drop would be expected to improve the performance of the filter, and therefore, do not cause the new tobacco product to raise different questions of public health. However, the new tobacco product uses FSC cigarette paper. The cigarette paper used on the new tobacco product also has a base paper porosity that is 6% higher than the cigarette paper used on the predicate tobacco product. Differences in the cigarette paper, including an increase in the base paper porosity and the addition of FSC bands, may affect smoke constituent yields including TNCO yields. Therefore, the differences in the cigarette paper, including the increase in base paper porosity and the addition of FSC bands, are deferred to chemistry to evaluate any potential effects these differences may have on the TNCO yields.

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 an engineering perspective.

#### **4.3. TOXICOLOGY**

A toxicology review was completed by Ryan Haskins on June 5, 2020.

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:

- Multiple ingredient increases in the tobacco filler

- Addition of (b) (4) mg/cigarette) and (b) (4) mg/cigarette) to the side seam adhesive
- Switch from non-FSC paper to FSC paper in the new tobacco product
- Analytically inequivalent 16% decrease in formaldehyde via CI and an analytically inequivalent 15% increase in CO via ISO

The tobacco filler ingredients increased by 0.2-0.7%, some of which are considered respiratory tract irritants. Pyrolysis of these ingredients may lead to an increased HPHC production. However, there is a decrease in measured formaldehyde smoke yields via CI smoking regimen and analytically equivalent smoke yields of acetaldehyde, acrolein, benzene, and B[a]P via both ISO and CI smoking regimens (other than the CO increase via ISO, which is likely due to the incorporation of FSC paper). (b) (4) and (b) (4) are added to the side seam adhesive of the new tobacco product. (b) (4) and (b) (4) fumes are known respiratory irritants. However, there is a lesser quantity of side seam adhesive in the new tobacco product compared to the predicate tobacco product. There are several ingredient additions and subtractions to the base paper, but this resulted in a net reduction in the overall base paper ingredients used in the new tobacco product. However, the addition of FSC bands to the base paper of the new tobacco product results in additional ingredients. Given the information available on the changes that have been observed in HPHC smoke yields of switching from non-FSC to FSC paper, the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the use of the FSC paper. The applicant provided measurements for acetaldehyde, acrolein, benzene, benzo[a]pyrene (B[a]P), carbon monoxide (CO), formaldehyde, nicotine, and tar measured under ISO and CI smoking regimens for the new and predicate tobacco products. There is an analytically inequivalent increase in CO smoke yields by the ISO smoking regimen and an analytically inequivalent decrease in tar and formaldehyde smoke yields by the CI smoking regimen in the new tobacco product compared to the predicate tobacco product, while the remaining HPHCs are analytically equivalent between the new and predicate tobacco products. The CO increase is likely due to the incorporation of FSC paper into the new tobacco product. The benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the use of the FSC paper. The analytically inequivalent decreases in tar and formaldehyde do not cause the new tobacco product to raise different questions of public health from a toxicological perspective.

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

An environmental review was completed by Bria Martin on May 18, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio, Jr., Ph.D. on May 19, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 19, 2020.

## 6. CONCLUSION AND RECOMMENDATION

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

- 6% increase in cigarette paper base paper porosity
- 25% increase in filter total denier
- 10% decrease in filter denier per filament
- 10% increase in filter density
- 34% increase in filter pressure drop
- Switch from non-FSC paper to FSC paper
- 15% increase in carbon monoxide (CO) on the ISO smoking regimen
- Addition of (b) (4) and (b) (4) to the side seam adhesive and reduction in the total side seam adhesive ingredients

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. An increase in the filter total denier and a decrease in the filter denier per filament would be expected to improve the performance of the filter. Similarly, an increase in the filter density and an increase in the filter pressure drop would be expected to improve the performance of the filter. An increase in the cigarette paper base paper porosity and the addition of FSC bands may affect smoke constituent yields, including TNCO yields. Based on the two one-sided t-test analysis, there is a 15% analytically inequivalent increase in CO smoke yields by the ISO smoking regimen and an 16% analytically inequivalent decrease in formaldehyde smoke yields by the CI smoking regimen. A decrease in the smoke yield does not cause the new tobacco product to raise different questions of public health. However, the increase in CO is consistent with switching from non-FSC to FSC paper. From a toxicological perspective, the benefit of using FSC cigarette paper in the new product to reduce household fires and personal injuries is anticipated to outweigh any potential increase in health risks from exposure to increased CO. The addition of (b) (4) mg/cigarette) and (b) (4) mg/cigarette) to the side seam adhesive is relatively small. In addition, there is an overall reduction in total side seam adhesive used in the new product. 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 tobacco 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. 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.

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 SE0015804, as identified on the cover page of this review.