

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

**SE0014202**

<b>SE0014202: Cheap Tobacco Menthol 100mm Size 200 Count</b>	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Ventilation	None
Characterizing Flavor	Menthol
<b>Common Attributes of SE Reports</b>	
Applicant	Midwest Tobacco Tube, Inc. dba Great Midwest Tube
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Filtered Cigarette Tubes
<b>Recommendation</b>	
Issue a Substantially Equivalent (SE) order.	

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2018.06.06 10:09:17 -04'00'

Matthew J. Walters, Ph.D., MPH  
CDR, U.S. Public Health Service  
Deputy 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: 2018.06.06 10:12:51 -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:

SE0014202: Cheap Tobacco Menthol 100mm Size 200 Count	
Product Name	Hot Rod Menthol King Size 200 Count
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	None
Characterizing Flavor	Menthol

The predicate tobacco product is a roll-your-own (RYO) filtered tube manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 18, 2017, FDA received one SE Report (SE0014202) from Midwest Tobacco Tube, Inc. dba Great Midwest Tube. FDA issued an acknowledgement letter on July 21, 2017. On September 29, 2017, FDA issued an advice/information request (A/I) letter. On November 28, 2017, FDA received the applicant's amendment (SE0014420) responding to FDA's A/I letter. FDA issued a Preliminary Finding (PFind) letter on February 20, 2018. On March 7, 2018, FDA received the applicant's amendment (SE0014571) responding to FDA's PFind letter. On March 30, 2018, FDA conducted teleconference with the applicant to clarify the requested environmental information. On April 5, 2018, FDA received the applicant's amendment (SE0014612) responding to FDA's additional environmental information request.

Product Name	SE Report	Amendments
Cheap Tobacco Menthol 100mm Size 200 Count	SE0014202	SE0014420 SE0014571 SE0014612

### 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 Brandon Rose on July 21, 2017.

The final review concludes that the SE Report is administratively complete.

### 3. COMPLIANCE REVIEW

The predicate tobacco product in SE0014202 was determined to be substantially equivalent by FDA under SE0001500. Therefore, this product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 April 2, 2018 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 Jiu Ai on September 14, 2017.

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 from a chemistry perspective. The review identified the following differences:

- Increased cigarette length (from 84 to 100mm)
- Increased cigarette paper ingredient quantities (~20%)
- Increased seam glue ingredient quantities (50%)
- Increased tobacco quantity<sup>1</sup> (18%)
- Differences in tipping paper ingredients and printing material

The new product is larger than the predicate product, thus there are increases in the amounts of ingredients in the new product compared to the predicate product. The cigarette paper contains increased amounts of all ingredients. Although there are higher amounts of all cigarette paper ingredients in the new product compared to the predicate product, the ingredient ratios relative to the total cigarette paper weight remains the same. Additionally, the seam adhesive in the new product contains 50% higher amounts of all ingredients compared to the predicate product. The impact on the seam glue quantity differences on product design is deferred to engineering. Additionally, there are differences in the tipping paper and printing material ingredients between the new and predicate products, however, these differences are insignificant as these are provided in the new and predicate products in µg or ng quantities, which would not materially affect the performance of the product. When 3R4F tobacco filler is added to the new and predicate products at a comparable packing density, the new product has 18% more tobacco than the predicate product. Furthermore, the filter of the new product has 60% more (b) (4) and 55% more (b) (4) than that of the predicate product. Despite the higher tobacco and filter ingredient amounts in the new product, the ISO and CI smoke yields for all particulate phase HPHC's (i.e., tar, nicotine, phenol<sup>2</sup>, and benzo[a]pyrene) were comparable or lower in the cigarettes tested using the new product

<sup>1</sup> When filled with 3R4F tobacco filler at a comparable packing density (0.26 g/cm<sup>3</sup>)

<sup>2</sup> Phenol is generally in the particulate phase of smoke.

because of the larger filter length, higher (b) (4) (b) (4) and higher (b) (4) in the new product. The ISO and CI smoke yields of volatile organic compound (VOC) HPHC's (i.e., 1,3-butadiene, acetaldehyde, benzene, isoprene, and toluene) are slightly higher from the cigarettes of the new product than from the cigarettes of predicate product due to less efficient filtration of the vapor phase HPHCs by the (b) (4) filter. However, these HPHC yields are not likely affected by the higher amounts of ingredients in cigarette paper and seam adhesive since these ingredients contribute to less than 5% of the overall mass of the actual tested tobacco product. The toxicological impact on the higher VOCs in mainstream smoke is deferred to toxicology.

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 related to product chemistry.

#### 4.2. ENGINEERING

Engineering reviews were completed by Julie Morabito on September 12, 2017 and by James Cheng on January 11, 2018.

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

- Increase in overall length (20%)
- Increase in filter length (25%)
- Increase in tipping paper length (25%)
- Increase in filter pressure drop (27%)
- Increase in filtered tube mass (52%)

The new product has a 10 mm longer tobacco rod than the predicate product, which allows the new product to contain a larger amount of tobacco and consequently a higher amount of available tobacco smoke constituents. However, the new product also incorporates a longer filter plug which allows for a higher filter efficiency that is intended to compensate for the higher amount of smoke constituents, resulting in smoke constituent yields comparable to those of the predicate product. The TNCO and HPHC data provided by the applicant show that the smoke constituent yields of the new and predicate products are comparable or only slightly higher, and as such, do not raise different questions of public health from an engineering perspective.

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 Eric Beier on September 22, 2017.

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 from a toxicology perspective. The review identified the following differences:

- Increased cigarette length (from 84 to 100 mm)
- Increased cigarette paper and seam glue ingredient quantities
- Increased VOC smoke yields under ISO and CI smoking regimens (i.e., acetaldehyde, acrolein (CI-only), 1,3-butadiene, acrylonitrile, benzene, isoprene, and toluene)

The new product is larger than the predicate product, thus there are increases in the amounts of ingredients in the new product compared to the predicate product. The cigarette paper contains increased amounts of all ingredients. Although there are higher amounts of all cigarette paper ingredients in the new product compared to the predicate product, the ingredient ratios relative to the total cigarette paper weight remains the same. Despite the higher ingredient amounts in the new product, the ISO and CI smoke yields for all particulate phase HPHC's (i.e., tar, nicotine, phenol, and benzo[a]pyrene) were comparable or lower in the cigarettes tested. The ISO and CI smoke yields of volatile organic compound (VOC) HPHC's (i.e., 1,3-butadiene, acetaldehyde, benzene, isoprene, and toluene) are slightly higher from the cigarettes of the new product than from the cigarettes of predicate product, however, these differences are within the analytical variability of the measurements and are not statistically significant.

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 related from a toxicology perspective.

#### 4.4. SOCIAL SCIENCE

A social science review was completed by Jennifer Bernat on September 6, 2017.

The social science review concludes that the new tobacco product has different characteristics compared to 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 review identified the following difference:

- Increased cigarette length (from 84 to 100 mm)

The social science review indicates that current available evidence suggests that changes in the length of the cigarette stick may influence consumer perceptions of the product; however, this is a filtered cigarette tube, and those studies do not examine perceptions of RYO cigarette tubes. From a social science perspective, at this time, there is insufficient scientific evidence on the influence of the length of filtered cigarette tubes on consumer perceptions to indicate that a change in length would cause the new product to raise different questions of public health. Therefore, the difference in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health related to consumer perception and use.

The review also evaluated the health information summary for the SE Report. FDA has determined that the health information summary provided for this SE Report would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco product into interstate commerce.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on February 16, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 6, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 6, 2018.

## 6. CONCLUSION AND RECOMMENDATION

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

- Increased length (from 84 to 100mm)
- Increased cigarette paper ingredient quantities (~20%)
- Increased seam glue ingredient quantities (50%)
- Increased tobacco quantity<sup>3</sup> (18%)
- Differences in tipping paper ingredients and printing material
- Increase in overall length (20%)
- Increase in filter length (25%)
- Increase in tipping paper length (25%)
- Increase in filter pressure drop (27%)
- Increase in filtered tube mass (52%)
- Increased VOC smoke yields under ISO and CI smoking regimens (i.e., acetaldehyde, acrolein (CI-only), 1,3-butadiene, acrylonitrile, benzene, isoprene, and toluene)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The major difference between the new and predicate tobacco products is the length of the cigarette tube – the predicate product is 84mm, whereas the new product is 100mm. With this increase in cigarette tube length, there were increases in cigarette paper and seam glue adhesive ingredients. The applicant demonstrated that these differences in ingredients do not raise different questions of public health by providing ISO and CI HPHC yields that showed minimal changes and were within the analytical variability of the measured analyte. The new product also incorporates a longer filter plug, which allows for a higher filter efficiency that is intended to compensate for the higher amount of smoke constituents, resulting in smoke constituent yields comparable or only slightly higher to those of the predicate product. 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.

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<sup>3</sup> When filled with 3R4F tobacco filler at a comparable packing density (0.26 g/cm<sup>3</sup>)

The predicate tobacco product was determined to be substantially equivalent by FDA under SE0001500.

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 SE0014202 was previously determined to be substantially equivalent by FDA under SE0001500. Comparison of the new tobacco product to the grandfathered product (Zen Menthol King Size 200 Count in SE0001500) reveals that the new tobacco product has the same differences in characteristics identified for the new and grandfathered tobacco products in SE0001500. Therefore, these differences do not cause the new tobacco product in SE0014202 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences between the new tobacco product in SE0001500 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0001500 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 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.

A SE order letter should be issued for the new tobacco product in SE0014202, as identified on the cover page of this review.