

Technical Project Lead (TPL) Review: SE0015755 - SE0015756

SE0015755: Bull Durham Blue 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
SE0015756: Bull Durham Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.06.09 14:35:54 -04'00'

Jeannie Jeong-Im, 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 Glen D. Jones -S
Date: 2020.06.09 15:23:22 -04'00'

For 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:

SE0015755: Bull Durham Blue 100MM	
Product Name	TOP Light 100MM Tubes
Package Type	Box
Portion Count	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
SE0015756: Bull Durham Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Portion Count	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None

The predicate tobacco products are roll-your-own (RYO) filtered cigarette tubes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 5, 2020, FDA received two SE Reports (SE0015755 and SE0015756) from Republic Tobacco, LP. On March 12, 2020, FDA issued an Acceptance letter to the applicant. On March 12, 2020 and March 24, 2020, FDA received amendments (SE0015773 and SE0015789, respectively) for SE0015756 in response to Office of Compliance and Enforcement (OCE) requests for information. On April 21, 2020, FDA received an amendment (SE0016213) for SE0015755 in response to an OCE request for information.

Product Name	SE Report	Amendments
Bull Durham Blue 100MM	SE0015755	SE0016213
Bull Durham Regular King Size	SE0015756	SE0015773 SE0015789

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 Fredris Wiley on March 10, 2020.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

OCE completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated April 5, 2020 for SE0015756 and May 8, 2020 for SE0015755, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated June 1, 2020 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

A chemistry review was completed by Robert F. Gahl on April 22, 2020.

The 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 differences:

SE0015755:

- Addition of (b) (4) (b) (4) mg/tube) in the plug wrap
- 82% increase (b) (4) mg/tube) in (b) (4) in the acetate tow
- 26% increase (b) (4) mg/tube) in (b) (4) in the filter
- Addition of (b) (4) (b) (4) mg/tube) in the tipping adhesive

SE0015756:

- 31% increase (b) (4) mg/tube) in (b) (4) in the acetate tow
- 58% increase (b) (4) mg/tube) in (b) (4) in the filter

- Addition of (b) (4) mg/tube) in the tipping adhesive

Both SE reports contain single ingredient information about the components of filtered roll-your-own cigarette tubes. There are increases in the ingredients in components that are not typically burned in the cigarette such as 26% - 58% increase in (b) (4) and addition of (b) (4) to the tipping adhesive. The applicant provided mainstream smoke yields for tar, nicotine, and carbon monoxide (TNCO) under the ISO and CI smoking regimens in the new and predicate tobacco products. (b) (4) collected the mainstream smoke data. Sufficient information about the methods and validation reports was provided. The mainstream smoke yields of TNCO in the new tobacco products were either analytically equivalent via TOST¹ or lower than the mainstream smoke yields in the corresponding predicate tobacco products in both SE reports. 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

An engineering reviews was completed by Michael Morschauer on April 21, 2020.

The 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 differences:

SE0015755

- Decrease in filter total denier (7%)

SE0015756

- Increase in overall tube weight (11%)
- Decrease in filter total denier (11%)
- Decrease in filter denier per filament (5%)
- Increase in filter pressure drop (43%)
- Increase in filter length (33%)

The applicant submitted target specifications and range limits for all necessary engineering parameters for each new and corresponding predicate tobacco product. For SE0015755, the new tobacco product has a decrease in filter total denier as compared to the corresponding predicate tobacco product. A difference in filter total denier may affect smoke constituent yields. Therefore, this difference was deferred to chemistry for evaluation of any potential effects it may have on smoke chemistry including tar and nicotine yields. For SE0015756, the new tobacco product has increases in overall tube weight, filter pressure drop, and filter length, and decreases in filter total denier and denier per filament as compared to the corresponding predicate tobacco product. A difference in overall tube weight may affect smoke constituent yields. Also, differences in filter total denier, denier per filament, pressure drop, and length may

¹ Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.

affect smoke constituent yields. Therefore, this difference was deferred to chemistry for evaluation of any potential effects it may have on smoke chemistry including tar, nicotine, and carbon monoxide. 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Vyomesh Patel on April 29, 2020.

The toxicology review concludes that the new tobacco products have different characteristics related to toxicology 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 differences:

- Tipping paper
 - (b) (4) is added in SE0015756 (b) (4) mg
 - (b) (4) are increased in SE0015756 (↑(b) (4) mg)
 - (b) (4) is added in SE0015755 (b) (4) mg and SE0015756 (b) (4) mg);
 - (b) (4) is added in SE0015756 (b) (4) mg); (b) (4) and
 - (b) (4) are added in SE0015755 (b) (4) mg)
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4)
 - (b) (4) is increased in SE0015755 (↑(b) (4) mg) and SE0015756 (↑(b) (4) mg)
 - (b) (4) is increased in SE0015756 mg (↑(b) (4) mg)
 - (b) (4) is increased in SE0015756 (↑(b) (4) mg) and added in SE0015755 (b) (4) mg)
 - (b) (4) are added to SE0015755 (b) (4) mg)
- Plug Wrap
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)
 - (b) (4) is increased in SE0015755 (↑(b) (4) mg) and SE0015756 (↑(b) (4) mg)
- Acetate Tow
 - (b) (4) and (b) (4) are added in SE0015755 (b) (4) mg)
 - (b) (4) is increased in SE0015755 (↑0.67 mg) and SE0015756 (↑(b) (4) mg)
 - (b) (4) is increased in SE0015755 and SE0015756 (↑(b) (4) mg)
 - (b) (4) is increased in SE0015756 (↑21.9 mg)
 - (b) (4) is increased in SE0015756 (↑(b) (4) mg)
- (b) (4)
 - (b) (4) is increased in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)
- Glue Filter
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)

- Tipping Glue
 - (b) (4) is added in SE0015755 (b) (4) mg) and SE0015756 (b) (4) mg)
 - (b) (4) is added in SE0015755 (b) (4) mg)
 - (b) (4) mg), (b) (4) mg) and (b) (4) mg)

There are many modifications to the ingredients in the new tobacco products. Although the components are not combusted, some of these ingredient changes may influence HPHC smoke yields in the new tobacco products upon pyrolysis. TNCO smoke yields generated by ISO and CI smoking regimens were provided for both the new and predicate tobacco products, and they were found analytically equivalent. 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on May 7, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio Jr., Ph.D., ATS, on May 27, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 27, 2020.

6. CONCLUSION AND RECOMMENDATION

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

SE0015755:

- Tipping paper
 - (b) (4) is added (b) (4) mg). (b) (4) and (b) (4) (b) (4) are added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) are added (b) (4) mg)
- Plug Wrap
 - (b) (4) added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (6) is added (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
- Acetate Tow
 - (b) (4) and (b) (4) are added (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
- (b) (4)
 - (b) (4) is increased (b) (4) mg)
- Glue Filter

- (b) (4) is added (b) (4) mg)
- Tipping Glue
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) mg), (b) (4) mg) and (b) (4) mg)
 - (b) (4) mg)
- Decrease in filter total denier (7%)

SE0015756:

- Tipping paper
 - (b) (4) and (b) (4) are increased (↑ (b) (4) mg)
 - (b) (4) mg), (b) (4) is added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
- Plug Wrap
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is added (b) (4) mg)
 - (b) (4) is added in SE0015756 (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
- Acetate Tow
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
 - (b) (4) is increased (↑ (b) (4) mg)
- Filter
 - (b) (4) is increased (b) (4) mg)
- Tipping Glue
 - (b) (4) is added (b) (4) mg).
 - (b) (4) mg), (b) (4) mg) and (b) (4) mg) are added
- Increase in overall tube weight (11%)
- Decrease in filter total denier (11%)
- Decrease in filter denier per filament (5%)
- Increase in filter pressure drop (43%)
- Increase in filter length (33%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. There are changes in ingredients to the tipping paper, plug wrap, acetate tow, filter, and tipping glue. These ingredients are not combusted and are not expected to contribute much to HPHCs in smoke. There are also changes in the denier per filament, pressure drop, and length, which may affect TNCO. The applicant provided TNCO of the new and predicate products of both of these SE Reports under ISO and CI smoking regimens. All the HPHCs were either equivalent under TOST or lower in the new products when compared to the corresponding predicate 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 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 SE0015755 and SE0015756, as identified on the cover page of this review.