# Technical Project Lead (TPL) Memorandum: SE Report SE0003200

| **New Tobacco Product** | |
|---|---|
| Product Name | Top Regular 100MM |
| Package Size | 200 tubes |
| Package Type | Box |
| Applicant | Republic Tobacco, L.P. |
| Status | Regular |
| Product Category | Roll-Your-Own Tobacco |
| Product Sub-Category | Filtered Cigarette Tubes |
| **Recommendation** | |
| Issue a Substantial Equivalence (SE) order | |

**Technical Project Lead (TPL):**

Digitally signed by Matthew R. Holman -S
Date: 2013.09.25 22:28:35 -04'00'

Matthew R. Holman, Ph.D.
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 David Ashley -S
Date: 2013.09.26 07:14:01 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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# 1. BACKGROUND

## 1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

**Table 1. Predicate Tobacco Product**

| | |
|---|---|
| Manufacturer | Republic Tobacco, L.P. |
| Product Name | Top Regular King Size |
| Package Size | 200 tubes |
| Package Type | Box |
| Product Category | Roll-Your-Own Tobacco |
| Product Sub-Category | Filtered Cigarette Tube |
| Claimed Status | Grandfathered Product |

## 1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original SE Report SE0003200 in May 2011. FDA sent the applicant an administrative advice and information request letter (A/I letter) for this SE Report. In response, the applicant submitted amendment SE0004260 to the original SE Report in April 2012. Following our review of the SE Report, we sent a scientific A/I letter to the applicant in August 2012. The applicant requested an extension to respond to the deficiencies identified in the scientific A/I letter. An extension was granted until February 2013. The applicant responded to the scientific A/I letter by amending their SE Report (SE0006321) in January 2013. On March 19 and 20, 2013, we had teleconferences with the applicant to clarify some pending issues. In response, the applicant submitted an additional amendment (SE0008148). We sent a preliminary finding letter to the applicant in June 2013 citing specific deficiencies to be addressed. The applicant responded to the preliminary finding letter by amending their SE Report (SE0009298).

## 1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0003200.

## 1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The new tobacco product has the following key differences compared to the predicate tobacco product:

- Increase in tube length (from 84 to 100 mm)
- Increase in filter length (from 15 to 25 mm)
- (b) (4)

- (b) (4)

The chemical compositions of the new and predicate tobacco products are nearly identical.

## 2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Devin Thomas, M.P.H. on February 29, 2012, and Stephanie Redus, M.S. on May 23, 2012.

The final administrative completeness review concluded that the SE Report was not administratively complete because a health information summary required under section 910(a)(4) of the FD&C Act was not provided. The SE Report is now administratively complete because, in October 2012, the applicant responded by stating that a health information summary will be made available upon request (SE0005021).

## 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 as of February 15, 2007). The OCE review dated May 23, 2012, and amended June 7, 2013, concludes that the predicate tobacco product is an eligible predicate tobacco product, as the applicant established that the predicate tobacco product is grandfathered.

The Office of Compliance and Enforcement (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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated September 20, 2013, 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

Chemistry reviews were completed by Michael Koenig, Ph.D. on August 9, 2012, and May 1, 2013.

The final chemistry review concludes that the new tobacco product does not raise different questions of public health with regard to product composition. The

chemical composition of the new product is nearly identical to that of the predicate product with the following exceptions:

- (b) (4)
- Increased amount of (b) (4) in the plug wrap

The (b) (4) should not adversely affect filter performance or toxicant yields when the tubes are smoked. Because (b) (4), listed as a (b) (4) of the plug wrap, and the plug wrap is not intended to be consumed or combusted during the process of smoking, the increase in this ingredient should not adversely affect product performance or toxicant yields. Overall, the chemistry review concludes that the differences in the identity or quantities of ingredients and additives between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health.

## 4.2. ENGINEERING

Engineering reviews were completed by Sabina Reilly on August 14, 2012, Christian Coyle on May 2, 2013, and Christian Coyle on August 30, 2013.

The final engineering review concludes that the new tobacco product does not raise different questions of public health with regard to product design. The design of the new and predicate tobacco products differ in the following ways:

- Increase in tube length (from 84 to 100 mm)
- Increase in tube mass (from 192 to 287 mg)
- Increase in tipping paper length (from 25 to 28 mm)
- Increase in filter length (from 15 to 25 mm)
- (b) (4)
- (b) (4)

The increase in tube mass is an expected outcome of increase tipping paper, filter, and overall tube length. It is unclear how much of the mass increase derives from the combusted material of the tube (i.e., cigarette paper and tipping paper that overlaps with cigarette paper). Generally, the following differences in characteristics identified in the SE Report may result in greater harmful and potentially harmful constituent (HPHC) yields when a tobacco product is smoked:

- An increase in combusted material (tipping paper and cigarette paper mass)
- An increase in tube length because more tobacco is smoked per cigarette

In this SE Report, these potential public health concerns are allayed by other product design characteristics. More specifically, the filter length is increased in the new tobacco product relative to the predicate tobacco product. The

(b) (4) Filter lengthening often decreases HPHC yields because the additional filter material captures increased amounts of HPHCs, reducing the amounts available in mainstream smoke. Similarly, (b) (4) can decrease HPHC yields by diluting mainstream smoke. Therefore, it is possible that the filter lengthening and (b) (4) compensates for the other product design features that might otherwise increase HPHC yield.

The (b) (4) data confirms that the product design changes do not increase HPHC yields when the product is smoked. (b) (4) There was a slight increase in the of the new tobacco product compared to the predicate tobacco product. The applicant also provided tar yields for both products. The new tobacco product produced (b) (4) tar under the (b) (4) than the predicate tobacco product. This in tar is consistent with the variability expected in smoking cigarette tubes hand packed with tobacco. In other words, this data indicates that there is not a significant difference in tar yields between the two tobacco products. Overall, the engineering review concludes that the differences in product design between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health.

### 4.3. TOXICOLOGY

A toxicology review was completed by Michael Orr, Ph.D. on July 26, 2012.

The toxicology review raises concern that (b) (4) higher in the new tobacco product compared to the predicate tobacco product. A deficiency regarding this issue was included in the scientific A/I letter. The deficiency is addressed in the chemistry review of the amendment received in response to the scientific A/I letter. As explained in the chemistry review, the higher quantity of (b) (4) in the new tobacco product reflects the increase filter length of the new tobacco product compared to the predicate tobacco product (i.e., 25 mm vs 15 mm in length). (b) (4) is used as a (b) (4) in the filter. Therefore, there are no differences in product toxicity between the predicate and new tobacco products, and the new tobacco product does not raise different questions of public health with regard to toxicity.

## 5. ENVIRONMENTAL DECISION

An environmental assessment was requested in the administrative A/I letter, which the applicant provided in its April 16, 2012 amendment. A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on September 25, 2013. The FONSI was supported by an environmental assessment prepared by Hoshing Chang, Ph.D. dated September 25, 2013.

## 6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products consist primarily of the following:

- Increase in tube length (from 84 to 100 mm)
- Increase in filter length (from 15 to 25 mm)
- (b) (4)
- (b) (4)

The chemical compositions of the new and predicate tobacco products are nearly identical. The (b) (4) data confirms that the product design changes do not increase HPHC yields when the product is smoked. (b) (4) . There was a slight increase in the of the new tobacco product compared to the predicate tobacco product. The applicant also provided tar yields for both products. The new tobacco product produced (b) (4) tar under the (b) (4) than the predicate tobacco product. This (b) (4) in tar is consistent with the variability expected in smoking cigarette tubes hand packed with tobacco. In other words, this data indicates that there is not a significant difference in tar yields between the two tobacco products. Overall, the engineering review concludes that the differences in product design between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health.

The applicant did not provide a health information summary. To fulfill the provisions of section 910(a)(4) of the FD&C Act, the applicant stated that it will make such information available upon request by any person.

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States 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 products are such that the new product does not raise different questions of public health. I concur with these reviews and recommend that an SE order be issued.

In addition, an order letter can be issued because FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order should be issued for the new tobacco product in SE0003200, as identified on the cover page of this memo.