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## Technical Project Lead (TPL) Memorandum: SE Report SE0003199

New Tobacco Product	
Product Name	Top Gold 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 22:25:39 -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 07:11:35 -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 Gold 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 SE0003199 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 SE0004157 to the original SE Report in February 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 (SE0006318) 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 (SE0008153). 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 SE0003199.

### 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)
- (b) (4)
- (b) (4)

- 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 January 3, 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
- Increased amount of (b) (4) in the cigarette paper

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 (b) (4) in this ingredient should not adversely affect product performance or toxicant yields. (b) (4)

. 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 200 to 305 mg)
- (b) (4)
- Increase in tipping paper length (from 25 to 28 mm)
- (b) (4)
- 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
- (b) (4)

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. (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)

(b) (4) There was a slight increase in the (b) (4) 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 (b) (4) 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 the concern that the (b) (4) may lead to increased toxicant exposure, but defers to the chemistry and engineering reviewers to address this concern. As stated in the previous section of this memo, the applicant satisfied this concern by submitting studies regarding the effect of (b) (4). 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 February 17, 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)
- (b) (4)
- (b) (4)
- 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)

(b) (4). There was a slight increase in the (b) (4) 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 SE0003199, as identified on the cover page of this memo.