



Technical Project Lead (TPL) Review:

SE0013916-SE0013925

SE0013916: High Card Regular 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013917: High Card Gold King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013918: High Card Menthol King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	Menthol
SE0013919: High Card Regular King Size	
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013920: Top Gold 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None

¹ As provided by applicant's certification statement. FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

SE0013921: Top Gold 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013922: Top Regular 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013923: Top Regular 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013924: Top Silver 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013925: Top Silver 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
Common Attributes	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.08.15 15:36:15 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2017.08.16 10:18:05 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND 5

 1.1. PREDICATE TOBACCO PRODUCTS 5

 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 7

 1.3. SCOPE OF REVIEW 7

2. REGULATORY REVIEW 7

3. COMPLIANCE REVIEW 8

4. SCIENTIFIC REVIEW 8

 4.1. SOCIAL SCIENCE 8

5. ENVIRONMENTAL DECISION..... 9

6. CONCLUSION AND RECOMMENDATION 9

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0013916: High Card Regular 100MM	
Product Name	High Card Regular 100MM (SE0004369)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013917: High Card Gold King Size	
Product Name	High Card Gold King Size (SE0004358)
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013918: High Card Menthol King Size	
Product Name	High Card Menthol King Size (SE0004374)
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	Menthol
SE0013919: High Card Regular King Size	
Product Name	High Card Regular King Size (SE0004370)
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None

SE0013920: Top Gold 100MM	
Product Name	Top Gold 100MM (SE0003199)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013921: Top Gold 100MM	
Product Name	Top Gold 100MM (SE0003199)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013922: Top Regular 100MM	
Product Name	Top Regular 100MM (SE0003200)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013923: Top Regular 100MM	
Product Name	Top Regular 100MM (SE0003200)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None
SE0013924: Top Silver 100MM	
Product Name	Top Silver 100MM (SE0010368)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None

SE0013925: Top Silver 100MM	
Product Name	Top Silver 100MM (SE0010368)
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Filter Ventilation	(b) (4)
Characterizing Flavor ¹	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 9, 2017, FDA received 10 Product Quantity Change SE Reports from Republic Tobacco, LP. FDA issued Acknowledgment letters to the applicant on March 2, 2017. FDA issued a Preliminary Finding letter on May 8, 2017. The applicant responded with amendment SE0014098.

Product Names	SE Report	Amendments
High Card Regular 100MM	SE0013916	SE0014098
High Card Gold King Size	SE0013917	
High Card Menthol King Size	SE0013918	
High Card Regular King Size	SE0013919	
Top Gold 100 MM	SE0013920	
Top Gold 100 MM	SE0013921	
Top Regular 100MM	SE0013922	
Top Regular 100MM	SE0013923	
Top Silver 100MM	SE0013924	
Top Silver 100MM	SE0013925	

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 Maria Suarez on March 2, 2017, and Sarah Webster on August 15, 2017.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Product Name	Predicate Product Found SE Under:	Date
SE0013916	High Card Regular 100MM	SE0004369	November 7, 2014
SE0013917	High Card Gold King Size	SE0004358	November 7, 2014
SE0013918	High Card Menthol King Size	SE0004374	November 7, 2014
SE0013919	High Card Regular King Size	SE0004370	November 7, 2014
SE0013920	Top Gold 100 MM	SE0003199	September 26, 2013
SE0013921	Top Gold 100 MM	SE0003199	September 26, 2013
SE0013922	Top Regular 100MM	SE0003200	September 26, 2013
SE0013923	Top Regular 100MM	SE0003200	September 26, 2013
SE0013924	Top Silver 100MM	SE0010368	March 27, 2015
SE0013925	Top Silver 100MM	SE0010368	March 27, 2015

The Office of Compliance and Enforcement 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 reviews dated August 3 and 10, 2017, conclude 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 discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on April 7, 2017.

The social science review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following difference between the new and predicate products:

- 25% increase in product quantity

The social science review concludes that the increase in product quantity from 200 to 250 tubes (25%) is not likely to influence consumer usage because the tubes are likely usage-invariant products. Therefore, the differences in product 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 social science perspective.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), increasing product quantity can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of the evidence provided in these SE Reports, as well as other scientific literature and FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the class of products at issue here—cigarette tubes—an increase in product quantity would not cause a new tobacco product to raise different questions of public health. As described in the social science review, for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), increasing the product quantity generally would not impact consumer use. Relatedly, although not evaluated by the social science reviewer for these particular SE Reports, scientific literature suggests that for consumer products that are "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), increasing the product quantity also generally would not impact consumer use.² Given the likelihood that cigarette tubes are usage-invariant (since there is no benefit of using an increased number of cigarette tubes per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space), I find that, based on the current state of the evidence, an increase of product quantity from 200 to 250 tubes does not cause the new products to raise different questions of public health.

The applicant submitted a health information summary. FDA has determined that statements provided for these SE Reports which are required in a health information summary pursuant to section 910(a)(4) of the FD&C Act do not constitute modified risk claims. The applicant's health information summary for each new tobacco product does not potentially violate section 911.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 15, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 15, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity from 200 filtered cigarette tubes to 250 filtered cigarette tubes (25% increase).

The social science review concludes that this difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco products were determined to be substantially equivalent by FDA under SE0003199, SE0003200, SE0004358, SE0004369, SE0004370, SE0004374, and SE0010368.

² Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. *Journal of Marketing Research*, 321-335.

The new tobacco products are currently in compliance with the FD&C Act.

FDA examined the environmental effects of finding the 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 SE0013916-SE0013925 as identified on the cover page of this review.