



Technical Project Lead (TPL) Review: SE0005838, SE0005840 and SE0008136-SE0008139

SE0005838: Tobacco Leaves Full Flavor Cigarette Tubes King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0005840: Tobacco Leaves Menthol Cigarette Tubes King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
SE0008136: ZICO Red Cigarette Tubes – King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0008137: ZICO Red Cigarette Tubes – 100mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0008138: ZICO Blue Cigarette Tubes – King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0008139: ZICO Green Cigarette Tubes – King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Silverfoiltubes International, Inc.
Report Type	Regular
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 Michael Koenig -S
Date: 2015.02.09 10:59:14 -05'00'

Michael L. Koenig, Ph.D.
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 David Ashley -S
Date: 2015.02.09 11:04:48 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND	4
1.1. PREDICATE TOBACCO PRODUCTS	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	5
1.3. SCOPE OF REVIEW	6
2. ADMINISTRATIVE REVIEW	6
3. COMPLIANCE REVIEW	6
4. SCIENTIFIC REVIEW	7
4.1. CHEMISTRY	7
4.2. ENGINEERING	7
4.3. SOCIAL SCIENCE	7
5. ENVIRONMENTAL DECISION	8
6. CONCLUSION AND RECOMMENDATION	8

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0005838: Tobacco Leaves Full Flavor Cigarette Tubes King Size	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Quantity	250
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0005840: Tobacco Leaves Menthol Cigarette Tubes King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Quantity	200
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
SE0008136: ZICO Red Cigarette Tubes – King Size	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Quantity	250
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0008137: ZICO Red Cigarette Tubes – 100mm	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Package Type	Box
Package Quantity	250
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0008138: ZICO Blue Cigarette Tubes – King Size	
Product Name	Zen Light Cigarette Tubes King Size
Package Type	Box
Package Quantity	250
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0008139: ZICO Green Cigarette Tubes – King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Quantity	200
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol

The predicate tobacco products are filtered cigarette tubes manufactured by Silverfoiltubes International, Inc.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant originally submitted these SE Reports in October 2012 (SE0005838 and SE0005840) and in March 2013 (SE0008136 – SE0008139). We sent the applicant administrative advice and information request (A/I) letters in February 2014 (SE0008136 – SE0008139) and in March 2014 (SE0005838 and SE0005840). In response to the administrative A/I letters, the applicant amended the SE Reports in March 2014 (SE0010312 – SE0010318). We sent the applicant a scientific A/I letter in August 2014. The applicant responded to the scientific A/I letter in October 2014 (SE0010706).

Product Name	SE Report	Amendments
Tobacco Leaves Full Flavor Cigarette Tubes King Size	SE0005838	SE0010316 SE0010547 SE0010706 SE0010817
Tobacco Leaves Menthol Cigarette Tubes King Size	SE0005840	SE0010318 SE0010429 SE0010453 SE0010547 SE0010706 SE0010817

Product Name	SE Report	Amendments
ZICO Red Cigarette Tubes – King Size	SE0008136	SE0010312 SE0010547 SE0010706 SE0010817
ZICO Red Cigarette Tubes – 100mm	SE0008137	SE0010313 SE0010547 SE0010706 SE0010817
ZICO Blue Cigarette Tubes – King Size	SE0008138	SE0010314 SE0010547 SE0010706 SE0010817
ZICO Green Cigarette Tubes – King Size	SE0008139	SE0010315 SE0010429 SE0010547 SE0010706 SE0010817

1.3. SCOPE OF REVIEW

This memo captures all administrative, compliance, and scientific reviews completed for SE0005838, SE0005840 and SE0008136-SE0008139.

2. ADMINISTRATIVE REVIEW

A first round of administrative completeness reviews was completed by Shireen Ahmad on February 26, 2014 (SE0008136 – SE0008139) and on March 5, 2014 (SE0005838, SE0005840). A second round of administrative completeness reviews was completed by Shireen Ahmad on March 26, 2014 (all six SE Reports).

The final completeness review concludes that the SE Reports are not administratively complete because the SE Reports did not include the “basis for the submitter’s determination that the new tobacco products are substantially equivalent (e.g., state same characteristics or different characteristics that do not raise new questions of public health).” However, in amendment SE0010547, the applicant stated that it believes the characteristics of the new and corresponding predicate tobacco products to be the same. Therefore, these SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products

are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated March 2014 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products 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 January 6, 2015, 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:¹

4.1. CHEMISTRY

Chemistry reviews were completed by Zhong Li on June 24, 2014, and by Tricia Johnson on December 4, 2014.

The final chemistry review concludes that the new tobacco products have the same characteristics related to composition as the corresponding predicate tobacco products. Therefore, the new tobacco products do not raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Ryan Foringer on June 30, 2014, and by Tiffany Petty on December 23, 2014.

The final engineering review concludes that the new tobacco products have design characteristics that are identical to those of the corresponding predicate tobacco products and, therefore, the new tobacco products do not raise different questions of public health.

4.3. SOCIAL SCIENCE

A social science review was completed by Alexander Persoskie on December 2, 2014.

The social science review concludes that the new tobacco products have different characteristics than the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different

¹ A toxicology review was not completed because the composition and design characteristics were determined to be the same for the new and corresponding predicate tobacco products.

questions of public health. Regarding social science, some of the new tobacco products differ from the corresponding predicate tobacco products in portions per package. The packaging size decreased from 250 filtered cigarette tubes per box to 200 filtered cigarette tubes per box for the new products in SE0005838 and SE0008136 – SE0008138. The social science review concludes that, although the change from 250 cigarette tubes per box to 200 cigarette tubes per box represents a 20% decrease in cigarette tubes per box, there is no available scientific evidence on the influence that the number of cigarette tubes per box has on consumer perceptions or use intentions to indicate that such a decrease would cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 30, 2015.² The FONSI was supported by an environmental assessment prepared by FDA on January 22, 2015.²

6. CONCLUSION AND RECOMMENDATION

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

- The number of filtered cigarette tubes per package is decreased from 250 to 200 in the new tobacco products relative to the corresponding predicate tobacco products (SE0005838 and SE0008136 – SE0008138).

The applicant has adequately demonstrated that this difference does not cause the new tobacco products to raise different questions of public health. The applicant explains the package size difference is due to different requirements from their purchasing clients; the predicate tobacco products are purchased by a different client than the new tobacco products. Furthermore, at this time, the social science review states that, in this case, there is no available scientific evidence regarding the influence that this difference in the number of cigarette tubes per box has on consumer perceptions or use intentions to indicate that such a decrease would cause the new tobacco products to raise different questions of public health. Therefore, the differences in package size between the new and corresponding predicate tobacco products in SE0005838 and SE0008136 – SE0008138 do not cause the new tobacco products to raise different questions of public health.

² The FONSI and environmental assessment include reference to SE0005839. FDA acknowledged withdrawal of this SE Report on January 29, 2015.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States 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.

In addition, order letters can be issued because FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant environmental impact.

SE order letters should be issued for the new tobacco products in SE0005838, SE0005840 and SE0008136 – SE0008139, as identified on the cover page of this review.