Technical Project Lead (TPL) Review: SE0002200, SE0002202, SE0002220

SE0002200: Vera Cruz Nocturne King Size Slim	
Package Type	Box
Package Quantity	200 tubes
Length	80 mm
Diameter	6.8 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0002202: Vera Cruz Midnight King Size Slim	
Package Type	Box
Package Quantity	200 tubes
Length	80 mm
Diameter	6.8 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0002220: Vera Cruz Elegante King Size Slim	
Package Type	Box
Package Quantity	200 tubes
Length	80 mm
Diameter	6.8 mm
Filter Ventilation	None
Characterizing Flavor	None
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 Matthew R. Holman -S
Date: 2016.05.02 10:18:35 -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: 2016.05.02 10:58:32 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002200	**Vera Cruz Nocturne King Size Slim**
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0002202	**Vera Cruz Midnight King Size Slim**
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0002220	**Vera Cruz Elegante King Size Slim**
Product Name	Zen Light Cigarette Tubes King Size
Package Type	Box
Package Quantity	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the SE Reports on March 16, 2011. It should be noted that these SE Reports were originally classified by FDA as provisional SE Reports. Section 910(a)(2)(B) of the FD&C Act includes the following requirements for an SE Report to be classified as provisional:

1. The SE Report is submitted to FDA by March 22, 2011.
2. The new tobacco product was "was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States" between February 16, 2007, and March 21, 2011.

Because these SE Reports were classified as provisional SE Reports, Public Health Impact (PHI) reviews were filed on December 6, 2012. In June 2013, the applicant submitted amendments to these SE Reports which, among other things, notified FDA that they had not yet commercially marketed the new tobacco products in the United States. Therefore, these SE Reports were reclassified by FDA as regular SE Reports because they do not meet the second requirement in section 910(a)(2)(B) of the FD&C Act.

FDA sent the applicant administrative Advice/Information (A/I) Request letters in May 2013. In response to the administrative A/I letters, the applicant amended all of the SE Reports in June 2013. FDA issued a Notification letter on April 4, 2014, indicating that substantive scientific review was expected to begin on May 20, 2014. On June 18, 2014, FDA held a teleconference with the applicant, and the applicant submitted an amendment on June 20, 2014 (SE0010547), containing a statement indicating whether or not the new tobacco products have the same or different characteristics that do not raise new questions of public health. FDA sent the applicant a scientific A/I letter covering all of the SE Reports in October 2014. The applicant responded to the scientific A/I letter in November 2014 (SE0010768) and in December 2014 (SE0010776 and SE0010788). On December 11, 2014, FDA sent the applicant an e-mail correspondence for additional information, and the applicant provided a response on December 15, 2014 (SE0010788), containing data sets. FDA issued a Preliminary Finding letter on February 25, 2015. On March 17, 2015, the applicant submitted an amendment in response to the Preliminary Finding letter (SE0011031). On May 1, 2015, FDA held a teleconference with the applicant, and the applicant submitted an amendment on May 2, 2015 (SE0011748), containing a revised cover letter to include a missing submission tracking number from the previous amendment in response to the Preliminary Finding letter dated March 17, 2015. On May 7, 2015, FDA held a teleconference with the applicant, and the applicant submitted an amendment on May 11, 2015 (SE0011838), containing additional information to fully evaluate the quality and acceptability of the TNCO testing data.

Product Name	SE Report	Amendments
Vera Cruz Nocturne King Size Slim	SE0002200	SE0009085 SE0010547 SE0010768 SE0010776 SE0010788 SE0011031 SE0011748 SE0011838
Vera Cruz Midnight King Size Slim	SE0002202	SE0009087 SE0010547 SE0010768 SE0010776 SE0010788 SE0011031 SE0011748 SE0011838
Vera Cruz Elegante King Size Slim	SE0002220	SE0009111 SE0010547 SE0010768 SE0010776 SE0010788 SE0011031 SE0011748 SE0011838

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews for SE0002200 and SE0002202 were completed by Tiffany Petty on May 21, 2013, by Shireen Ahmad on January 2, 2014, and by Aden Asefa on December 12, 2014. Regulatory reviews for SE0002220 were completed by Tiffany Petty on May 30, 2013, by Shireen Ahmad on September 26, 2013, and by Aden Asefa on December 12, 2014.

The final reviews conclude that the 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 April 28, 2014, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (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 April 27, 2016 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

Chemistry reviews were completed by Zhong Li on July 18, 2014, and by Tricia Johnson on January 26, 2015, and May 20, 2015.

The final chemistry review concludes that the new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

- Product quantity changed from 200 to 250 filtered cigarette tubes per box[1]

The packaging materials used in the new and predicate tobacco products are identical. Therefore, the minor differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. It should be noted that the chemistry review did evaluate submitted HPHC data and found the data to be accurate (see section 4.2 of this review for discussion of HPHC results).

4.2. ENGINEERING

Engineering reviews were completed by Ryan Foringer and Tiffany Petty on July 23, 2014, and by Tiffany Petty on January 14, 2015, and May 19, 2015.

The final engineering review concludes that the new tobacco products have different characteristics related to product design 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 engineering review

[1] It should be noted that the package quantity change was actually a decrease from 250 to 200 filtered cigarette tubes per box.

identified the following significant differences in design between the new and corresponding predicate tobacco products:

- Product quantity and brand name
- Decreased tube length ([redacted])
- Decreased tube diameter ([redacted])
- Decreased tube mass ([redacted]) [SE0002200 & SE0002202 only]
- Increased base paper porosity ([redacted]) [SE0002220 only]
- Increased filter density ([redacted])
- Increased pressure drop ([redacted])
- Increased filter length [redacted] [SE0002220 only]

These differences in design generally would be expected to decrease HPHC yields. This was confirmed by HPHC test data submitted in the SE Reports that demonstrated significant decreases in tar and nicotine yields under the ISO smoking regimen for all three new tobacco products relative to the corresponding predicate tobacco products. Therefore, the differences in characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. The engineering review did not evaluate the label (brand name).

4.3. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on February 17, 2015.

The final social science review concludes that the new tobacco products have different characteristics related to consumer perception 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 social science review focused on the decrease in package quantity from 250 to 200 tubes in the new and corresponding predicate tobacco products. However, the social science review concludes that 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 from 250 to 200 would cause the new tobacco products to raise different questions of public health from a social science perspective.

4.4. ADDICTION

An addiction review was completed by Lingling Guan on May 29, 2015.

The final addiction review concludes that the new tobacco products do *not* have different characteristics related to addiction compared to the corresponding predicate tobacco products.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 28, 2016. The FONSI was supported by an environmental assessment prepared by FDA on March 28, 2016.

6. CONCLUSION AND RECOMMENDATION

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

- Decreased tube length ((b)(4))
- Decreased tube diameter ((b)(4))
- Decreased tube mass ((b)(4)) [SE0002200 & SE0002202 only]
- Increased base paper porosity ((b)(4)) [SE0002220 only]
- Increased filter density ((b)(4))
- Increased pressure drop ((b)(4))
- Increased filter length ((b)(4)) [SE0002220 only]
- Decrease in package quantity (20%)

The applicant has adequately demonstrated that the changes in product design do not cause the new tobacco products to raise different questions of public health. The differences in design were expected to decrease HPHC yields and this was confirmed by test data submitted in the SE Reports that demonstrated significant decreases in tar and nicotine yields under the ISO smoking regimen for all three new tobacco products relative to the corresponding predicate tobacco products.

The applicant has adequately demonstrated that the change in product quantity does not cause the new tobacco products to raise different questions of public health. The applicant explains the difference in product quantity is due to (b)(4); the predicate tobacco products are (b)(4) than the new tobacco products. Furthermore, the social science review states that 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 of 250 to 200 would cause the new tobacco products to raise different questions of public health. Therefore, the differences in design characteristics do not cause the new tobacco products to raise different questions of public health. I concur with the scientific reviews and recommend that SE order letters be issued.

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.
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 SE0002200, SE0002202, and SE0002220, as identified on the cover page of this review.