



Technical Project Lead (TPL) Memorandum: SE Reports SE0004606-SE0004610

SE0004606: FasFil King Size Red Cigarette Tubes	
Length	84 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
SE0004607: FasFil King Size Blue Cigarette Tubes	
Length	84 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
SE0004608: FasFil King Size Menthol Cigarette Tubes	
Length	84 mm
Package Quantity	200 tubes
Package Type	Box
Ventilation	Unventilated
SE0004609: FasFil 100mm Size Red Cigarette Tubes	
Length	100 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
SE0004610: FasFil 100mm Size Blue Cigarette Tubes	
Length	100 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
Common Attributes of SE Reports	
Applicant	Silverfoiltubes International, Inc.
Report Type	Regular
Product Category	Roll-your-own tobacco
Product Sub-Category	Filtered tubes
Recommendation	
Issue Substantial Equivalence (SE) orders	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S

Date: 2014.06.18 21:52:07 -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: 2014.06.19 06:27:16 -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 products:

Table 1. Predicate Tobacco Products

FasFil King Size Red Cigarette Tubes (SE0004606)	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Length	84 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
FasFil King Size Blue Cigarette Tubes (SE0004607)	
Product Name	Zen Light Cigarette Tubes King Size
Length	84 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
FasFil King Size Menthol Cigarette Tubes (SE0004608)	
Product Name	Zen Menthol Cigarette Tubes King Size
Length	84 mm
Package Quantity	200 tubes
Package Type	Box
Ventilation	Unventilated
FasFil 100mm Size Red Cigarette Tubes (SE0004609)	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Length	100 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated
FasFil 100mm Size Blue Cigarette Tubes (SE0004610)	
Product Name	Zen Light Cigarette Tubes 100mm
Length	100 mm
Package Quantity	250 tubes
Package Type	Box
Ventilation	Unventilated

The predicate tobacco products are manufactured by Silverfoiltubes International, Inc. They are roll-your-own tobacco cigarette tubes.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the five original SE Reports listed in Table 2 of this memo. We sent the applicant administrative advice and information request letters (A/I letters) for these SE Reports. In response, the applicant submitted

amendments to the original SE Reports (see Table 2). Following our review of the original and amended SE Reports, we sent a scientific A/I letter to the applicant in December 2013. The applicant responded to the scientific A/I letter by amending their SE Reports (see Table 2).

Table 2. SE Reports and Amendments

Product Name	SE Report	Amendments
FasFil King Size Red Cigarette Tubes	SE0004606	SE0005495 SE0010224 SE0010333
FasFil King Size Blue Cigarette Tubes	SE0004607	SE0005498 SE0010224 SE0010333
FasFil King Size Menthol Cigarette Tubes	SE0004608	SE0005496 SE0010224 SE0010333
FasFil 100mm Size Red Cigarette Tubes	SE0004609	SE0005499 SE0010224 SE0010333
FasFil 100mm Size Blue Cigarette Tubes	SE0004610	SE0005497 SE0010224 SE0010333

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0004606-SE0004610. It should be noted that the scientific reviews discussed in this memo evaluated SE0004606^{(b) (4)}. Therefore, some of the deficiencies in the scientific reviews may address these ^(b) SE Reports, but this memo only addresses SE0004606-SE0004610.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

- Package quantity decrease (SE0004606, SE0004607, SE0004609, SE0004610 only)
- ^{(b) (4)}

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed as follows:

- SE0004606, SE0004607: by Laila Noory, M.P.H. on November 21, 2012, and Chellee Cephas on January 28, 2013
- SE0004608, SE0004609, SE0004610: by Chellee Cephas on November 26, 2012, and January 28, 2013

The final administrative completeness review concludes that these SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews for SE0004606, SE0004608, and SE0004610 on March 20, 2013, for SE0004607 on March 19, 2013, and for SE0004609 on May 30, 2013, 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 review concludes that the predicate tobacco products are eligible predicate tobacco products, as the applicant has established that the predicate tobacco products are grandfathered.

The Office of Compliance and Enforcement (OCE) also completed reviews 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 May 15, 2014, 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 disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Zhong Li, Ph.D. on June 3, 2013, and April 25, 2014.

The final chemistry review concludes that the new tobacco products do not raise different questions of public health with regard to product composition. The significant product composition issue identified during the scientific review of the SE Reports was inadequate information required to fully characterize all ingredients in the new and predicate tobacco products. In response to FDA's scientific A/I letter, the applicant provided the appropriate characterization of the ingredients and materials used in the new and predicate tobacco products.

Based on the information provided by the applicant, identical sub-components of the filters and tubes are utilized in the new and corresponding predicate products in all six of the SE Reports. The difference in the package design does not cause the new products to raise different questions of public health. Therefore, the final chemistry review concludes that the new tobacco products do not raise different questions of public health with regard to product composition.

4.2. ENGINEERING

Engineering reviews were completed by Komal Ahuja on June 3, 2013, April 25, 2014, and May 29, 2014.

The final engineering review concludes that the new tobacco products do not raise different questions of public health with regard to product design. The significant product design issue identified during the scientific review of the SE Reports was inadequate information required to fully characterize the new and predicate tobacco products. In response to FDA's scientific A/I letter, the applicant provided the appropriate information and data to fully characterize the new and predicate tobacco products. Based on the information and data provided by the applicant, the new and corresponding predicate products are identical in product design. Therefore, the final engineering review concludes that the new tobacco products do not raise different questions of public health with regard to product design.

4.3. TOXICOLOGY

Toxicology reviews were completed by Hans Rosenfeldt, Ph.D., on September 6, 2013, and May 30, 2014.

The final toxicology review concludes that the new tobacco products do not raise different questions of public health with regard to product toxicity. The review focused on the toxicity of the following ingredients:

 (b) (4)

The review concluded that the low level of exposure to these chemicals would not cause the new products to raise different questions of public health. Therefore, the toxicology review concludes that the new tobacco products do not raise different questions of public health.

5. ENVIRONMENTAL DECISION

An environmental assessment was provided by the applicant. A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 29, 2014. The FONSI was supported by an environmental assessment prepared by Ronald Edwards, M.S. dated May 28, 2014.

6. CONCLUSION AND RECOMMENDATION

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

- Package quantity decrease (SE0004606, SE0004607, SE0004609, SE0004610 only)
- (b) (4)

The new and corresponding predicate products are essentially identical with the exception of the above differences. And, the differences that do exist are minor and inconsequential with regard to public health.

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 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 SE0004606-SE0004610, as identified on the cover page of this memo.