Technical Project Lead (TPL) Review: SE0010112

SE0010112: Silver Tip Extra 250	
Package Type	Cardboard box
Package Quantity	250 tubes
Length	84 mm
Width	28 mm
Diameter	8.0 mm
Filter Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	GIZEH Raucherbedarf GmbH
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.10.07 09:22:49 -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: 2015.10.07 09:36:29 -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 PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0010112: Silver Tip Extra 250	
Product Name	Silver Tip 250
Package Type	Cardboard box
Package Quantity	250 tubes
Length	84 mm
Width	24 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

The predicate tobacco product is a roll-your-own tobacco filtered cigarette tube manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 6, 2013, the applicant submitted the SE Report. On January 16, 2014, the applicant submitted an amendment in response to FDA's request for additional information to identify the new tobacco product (SE0010114). An Acknowledgement letter was issued on January 31, 2014. On February 3, 2014, and March 20, 2014, FDA held teleconferences with the applicant and requested additional information to uniquely identify the predicate tobacco product. In response to the teleconferences, the applicant submitted an amendment (SE0010321) received on March 24, 2014. An Advice/Information (A/I) Request letter was issued on March 19, 2014. The applicant responded on April 10, 2014, by submitting an amendment (SE0010400); the applicant submitted an additional amendment (SE0010477) on May 12, 2014 to supplement some of the information included in SE0010321. FDA issued a Notification letter on April 4, 2014, informing the applicant that scientific review was expected to begin on May 20, 2014. FDA sent the applicant an A/I letter on September 17, 2014. The applicant responded with an amendment (SE0010748) on November 17, 2014. FDA issued a Preliminary Finding letter on February 13, 2015. The applicant responded by submitting an amendment (SE0011022) on March 13, 2015. On May 4, 2015, the applicant submitted an amendment (SE0011720) with additional information requested by the FDA regarding the burning agent, (b) (4) seam adhesive in the new and predicate tobacco products. On June 25, 2015, FDA emailed the applicant a list of questions and placed a telephone call on June 26, 2015, to confirm that the applicant received the questions, which required responses in order to finalize the Environmental Assessment. The applicant responded by submitting amendment SE0012044 on July 2, 2015 and amendment SE0012046 on July 6, 2015.

Product Name	SE Report	Amendments
Silver Tip Extra 250	SE0010112	SE0010114 SE0010321 SE0010400 SE0010401 SE0010477 SE0010748 SE0011022 SE0011720 SE0012044 SE0012046

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

Regulatory completeness reviews were completed by Alexis Morgan on March 14, 2014, and May 21, 2014.

The final completeness review concludes that the SE Report is administratively complete.

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 April 30, 2014, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is an eligible predicate tobacco product.

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 June 4, 2015[1], concludes that the new tobacco products are in compliance with the FD&C Act.

[1] An addendum to this review was completed on July 22, 2015, to confirm that the applicant is not in arrears on User Fees.

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 Changyu Chae on August 13, 2014, January 6, 2015, and May 8, 2015.

The final chemistry review concludes that the new tobacco product has different characteristics related to product composition compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health from a chemistry perspective. There were differences in many ingredient quantities in the [redacted] and [redacted] of the new and predicate tobacco products. However, when the new and predicate tobacco products were filled with the same tobacco filler and smoked under the ISO and Canadian Intense smoking regimens, the tar, nicotine, and carbon monoxide yields are lower in the new tobacco product than the predicate tobacco product. Therefore, the differences in characteristics related to product composition between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by James Cheng on August 19, 2014, December 29, 2014, and May 4, 2015.

The final engineering review concludes that the new tobacco product has different characteristics related to product design compared to the predicate tobacco products but the differences do not cause the new tobacco product to raise different questions of public health from the engineering perspective. The review identifies the following key differences in characteristics between the new and predicate tobacco products:

- Increased tube mass (from [redacted] mg to [redacted] mg)
- Increased filter length (from (b) (4) mm to (b) (4) mm)
- Increased tipping paper (from (b) (4) mm to (b) (4) mm)
- Increased filter denier (from [redacted] DPF/[redacted] TD to [redacted] DPF[redacted] TD)
- Increased filter pressure drop (from (b) (4) mm H_2O to (b) (4) mm H_2O)

When the new and predicate tobacco products were filled with the same tobacco filler and smoked under the ISO and Canadian Intense smoking regimens, the tar, nicotine, and carbon monoxide yields are lower in the new tobacco product than the predicate tobacco product. Therefore, the differences in characteristics related to product design between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

4.3. TOXICOLOGY

Toxicology reviews were completed by James Hobson on February 13, 2015, and by Carmine Leggett on May 13, 2015.

The final toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review evaluated differences in the product composition and design characteristics identified in sections 4.1 and 4.2 of this review. Similar to the chemistry and engineering reviews, the final toxicology review discusses the lower tar, nicotine, and carbon monoxide yields in the new tobacco product compared to the predicate tobacco product (when both products are filled with the same tobacco filler). Therefore, the differences in characteristics related to toxicology between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 5, 2015. The FONSI was supported by an environmental assessment prepared by FDA on October 5, 2015.

6. CONCLUSION AND RECOMMENDATION

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

- Changes to (b) (4) ingredients
- Increased tube mass (from (b) (4) mg to (b) (4) mg)
- Increased filter length (from (b) (4) mm to (b) (4) mm)
- Increased tipping paper (from (b) (4) mm to (b) (4) mm)
- Increased filter denier (from (b) (4) DPF/(b) (4) TD to (b) (4) DPF/(b) (4) TD)
- Increased filter pressure drop (from (b) (4) mm H_2O to (b) (4) mm H_2O)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The chemistry, engineering, and toxicology reviews conclude that these differences do not cause the new tobacco products to raise different questions of public health because lower tar, nicotine, and carbon monoxide yields were produced by the new tobacco product compared to the predicate tobacco product (when both products are filled with the same tobacco filler). I concur with these reviews.

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.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0010112, as identified on the cover page of this review.