Technical Project Lead (TPL) Memorandum: SE Report SE0001698

New Tobacco Product	
Product Name	Elements Aficionado 1 and ¼
Package Size	50 papers and tips
Package Type	Box
Applicant	HBI International
Status	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling paper and paper tips
Recommendation	
Issue a Substantial Equivalence (SE) order	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2013.09.25 22:33:07 -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: 2013.09.26 07:08:38 -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:

Table 1. Predicate Tobacco Products

Manufacturer	HBI International
Product Name	Elements 1 and ¼ & Elements Tips
Package Size	50 papers and tips
Package Type	Box
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling paper and paper tips
Claimed Status	Grandfathered Product

Originally, the applicant did not identify a predicate tobacco product for the paper tips. However, in response to the August 2012 scientific advice/information request letter (A/I letter), the applicant identified Elements Tips as the predicate tobacco product for paper tips. The applicant originally identified the predicate tobacco product for the rolling paper as (b) (4) . However, when communicating with OCE to establish the predicate tobacco product as grandfathered, the applicant changed the predicate tobacco product for the rolling paper to Elements 1 and ¼. Because OCE allowed the applicant to change the predicate tobacco product, OS evaluated the substantial equivalence of the new tobacco product to Elements 1 and ¼.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original SE Report SE0001698 in April 2011. FDA sent the applicant an administrative advice/information request letter (A/I letter) for this SE Report in January 2012. In response, the applicant submitted amendment SE0004216 to the original SE Report in March 2012. Following our review of the original and amended SE Report, we sent a scientific A/I letter to the applicant in August 2012. The applicant requested an extension to respond to the deficiencies identified in the scientific A/I letter. An extension was granted until February 2013. The applicant responded to the scientific A/I letter by amending their SE Report (SE0007215) in February 2013. In April 2013, we had a teleconference with the applicant to clarify some pending issues. In response, the applicant submitted an additional amendment (SE0008323). On June 26, 2013, we had another teleconference with the applicant to request an ingredients list for paper. In response, the applicant submitted additional amendments (SE0009297 and SE0009807). On September 19, 2013, we had an additional call with the applicant to request a statement for action to comply with Section 907 of the FD&C Act. In response, the applicant submitted an additional amendment (SE0009810).

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0001698.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACCO PRODUCTS

The rolling paper and paper tips in the new tobacco product are nearly identical to those in the predicate tobacco products. The new tobacco product co-packages the two predicate tobacco products (rolling paper and paper tips) into a single product.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Marcella White, M.S., on January 11, 2012, and December 19, 2012.

The final administrative completeness review concluded that the SE Report was not administratively complete for the following reasons:

1. Full identification of the new tobacco product is not provided because the quantity is omitted.

2. The applicant states that the heating source is identical for the new and predicate tobacco products but does not provide a description of the heating source.

3. The applicant does not provide a statement of compliance with standards under section 907 of the FD&C Act.

As explained in a memo by Cristi Stark, M.S. dated September 25, 2013, this information has been provided and the SE Report is currently 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 products are a grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE review dated May 23, 2012 concludes that the predicate tobacco products are eligible predicate tobacco products, as the applicant established that the predicate tobacco products are grandfathered.

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 August 28, 2013, 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 Ciby Abraham, Ph.D. on August 9, 2012, and Candice Jongsma, Ph.D. on July 22, 2013.

The final chemistry review concludes that the new tobacco product does not raise different questions of public health with regard to product composition. The composition of the new tobacco product is identical to the composition of the predicate tobacco products with the only difference being that two predicate tobacco products are packaged together in the new tobacco product.

4.2. ENGINEERING

Engineering reviews were completed by Sabina Reilly on August 9, 2012, and James Cheng on July 22, 2013.

The final engineering review concludes that the new tobacco product does not raise different questions of public health with regard to product design. The rolling paper in the new tobacco product uses the same paper with the same dimensions as that in the paper predicate tobacco product. The paper tips in the new tobacco product use the same paper as those in the paper tips predicate tobacco product with only slight dimensional changes from that predicate tobacco product. These minor dimensional differences do not affect product performance. Overall, the engineering review concludes that the minor differences in product design between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health.

4.3. TOXICOLOGY

A toxicology review was completed by Michael Orr, Ph.D., DABT on June 28, 2012.

The toxicology review concludes that the new tobacco product does not raise different questions of public health with regard to product toxicity.

5. ENVIRONMENTAL DECISION

An environmental assessment was requested in the administrative A/I letter, which the applicant provided in its March 11, 2012, amendment. A finding of no significant impact (FONSI) was signed by RADM David L. Ashley on September 25, 2013. The FONSI was supported by an environmental assessment prepared by Hoshing Chang, Ph.D. dated September 25, 2013.

6. CONCLUSION AND RECOMMENDATION

The rolling paper and paper tips in the new tobacco product are nearly identical to those in the predicate products. The new tobacco product co-packages the two predicate tobacco products (rolling paper and paper tips) into a single product.

The rolling paper in the new tobacco product uses the same paper with identical dimensions as that of the paper predicate tobacco product. The paper tips in the new tobacco product use the same paper as those in the paper tips predicate tobacco product with only slight dimensional changes from the predicate tobacco product. These minor dimensional differences do not affect product performance. Therefore, the minor differences in product design between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of 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 product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new product does not raise different questions of public health. I concur with these reviews and recommend that an SE order be issued.

In addition, an order letter can be issued because FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order should be issued for the new tobacco product in SE0001698, as identified on the cover page of this memo.