FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015150

SE0015150: Double Dutch Tips	
Package Type	Book
Package Quantity	100 Tips
Length	58.5 mm
Width	18.5 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Paper Tip
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.09.25 10:35:35 -04'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
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 Glen D. Jones -S
Date: 2019.09.25 11:33:37 -04'00'

For Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco product:

SE0015150: Double Dutch Tips	
Product Name	Elements Tips Original
Package Type	Book
Package Quantity	50 Tips
Length	51.0 mm
Width	17.5 mm
Characterizing Flavor	None

The predicate tobacco product is a roll-your-own (RYO) paper tip manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 1, 2019, FDA received an SE Report from BBK Tobacco & Foods LLP dba HBI International. FDA issued an Acknowledgment letter to the applicant on April 9, 2019. On April 26, 2019, (SE0015208), May 01, 2019 (SE0015211), May 13, 2019 (SE0015231), May 16, 2019 (SE0015234), FDA received amendments in response to requests from the Office of Compliance and Enforcement. FDA issued an Advice/Information Request (A/I) letter on May 31, 2019. On June 27, 2019, FDA received the applicant's response to the A/I letter (SE0015275).

Product Name	SE Report	Amendments
Double Dutch Tips	SE0015150	SE0015208 SE0015211 SE0015231 SE0015234 SE0015275

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A Regulatory review was completed by Kaylene Charles on April 9, 2019.

The final 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 May 22, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 September 3, 2019, concludes that the new tobacco product is 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

A chemistry review was completed by An T. Vu on May 17, 2019.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry 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 identified the following differences:

- Increase in product dimensions: (b) (4) versus (b) (4)
- Heavier paper basis weight: (b) (4)
- Increases in amount of (b) (4) ingredients
- Increase in package quantity: (b) (4)
- Decrease in case quantity: (b) (4)

The new RYO paper tip is larger, heavier, and contains higher amounts of (b) (4) ingredients than the predicate RYO paper tip. When rolled and assembled into RYO cigarettes, the slightly longer new paper tip could lead to a small decrease in tobacco quantity, which could slightly reduce HPHC smoke yields. Additionally, unlike (b) (4), rolled paper tips have open structure and are not intended to be combusted. Therefore, even with the increases in ingredient quantities, use of the new tobacco product is not anticipated to contribute to HPHC smoke yields. The increase in package quantity and/or decrease in case quantity for the new tobacco product also does not raise concerns because a unit of use for the new and predicate tobacco products is an individual paper tip.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Nashaat Rasheed on May 22, 2019 and on August 13, 2019.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering 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 identified the following differences:

- 6% increase in paper tip width
- 13% decrease in paper tip length

The difference in paper tip length may affect the pressure drop, paper porosity and/or overall ventilation based on the rolling of the paper tip, which may affect smoke constituent yields. The engineering review deferred evaluation of HPHC information to the chemistry review. But HPHC information was not provided. However, the chemistry review determined that HPHC data was not necessary to evaluate the SE report because the new tobacco product is not combusted and would result in less tobacco being burned in a finished RYO cigarette, which would not adversely affect smoke chemistry.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Jonathan Fallica on May 22, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to toxicology compared to the corresponding predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- 18% per gram of paper increase in (b) (4)
- 17% per gram of paper decrease in (b) (4)
- 33% per gram of paper decrease in (b) (4)

The toxicology review determined that, because the rolling paper tips will be used in the unburned section of a RYO cigarette, these paper tip ingredient quantity differences do not cause the new product to raise different questions of public health.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 14, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 14, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Increase in product dimensions: (b) (4)
- Heavier paper basis weight: (b) (4)
- Increases in amount of (b) (4) ingredients
- Increase in package quantity: (b) (4)
- Decrease in case quantity: (b) (4)
- 6% increase in paper tip width
- 13% decrease in paper (b) (4)
- 18% per gram of paper increase in (b) (4)
- 17% per gram of paper decrease in (b) (4)
- 33% per gram of paper decrease in (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The new tobacco product is not anticipated to adversely affect smoke chemistry because it is a non-combusted component used in RYO cigarettes and its increased size. The latter should actually cause less tobacco to be packed into RYO cigarettes and combusted; and should favorably affect smoke chemistry. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets 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 tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

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

An SE order letter should be issued for the new tobacco products in SE0015150, as identified on the cover page of this review.