FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of SE Report

New Product Subject of this Review	
Submission tracking number (STN)	SE0015654
Common Attributes	
Submission date	January 22, 2020
Receipt date	January 22, 2020
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International and IBERPAPEL S.L
Application type	Regular
Product category	Roll-Your-Own Tobacco Products
Product subcategory	Rolling Paper
Cross-Referenced Submissions	
SE0015654	(b)(4)
Supporting FDA Memoranda Relied Upon in this Review	
SE0015654	• Memorandum, Equivalence Testing for SE Evaluation (February 24, 2017). • Review of Saccharides as Tobacco Ingredients. (July 17, 2017) • Harmful and potentially harmful constituent (HPHC) comparison and evaluation procedure for comparing two tobacco products in the substantial equivalence reports (February 19, 2019). • Addendum to February 24, 2017, Equivalence Testing for SE Evaluations Memo (April 16, 2019) • Addendum to Memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 31, 2019)
Recommendation	
Issue a Substantially Equivalent (SE) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Karen M. Coyne -S
Date: 2021.05.26 15:57:46 -04'00'

Karen Coyne, Ph.D.
Associate Director, Division of Product Science
Office of Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.05.26 18:14:24 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in Appendix A.

1.2. REGULATORY ACTIVITY

On January 29, 2020, FDA issued an Acceptance letter. On March 30, 2020, FDA issued a Deficiency letter to the applicant. On April 17, 2020, FDA issued an Extension Granted letter. See Appendix B for amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new product that are the subject of this review. The second cycle toxicology and environmental reviews incorrectly identify the application submission and receipt dates as August 6, 2019. The correct submit and receipt dates are January 22, 2020, as noted on the cover page of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Cynthia Colon	1/29/2020	Not assigned	N/A
Chemistry	Rachel Lerebours	3/16/2020	Not assigned	N/A
Engineering	Pritesh Darji	3/16/2020	Not assigned	N/A
Toxicology	Daniel Beury	3/19/2020	Atinuke Seun Ajiboye	4/20/2021
Environmental Science	Thomas Creaven	3/4/2020	Vyomesh Patel	4/20/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate product is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007). The OCE review dated February 11, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate product is grandfathered and, therefore, is an eligible predicate product.

OCE also completed a review to determine whether the new product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 26, 2021, concludes that the new product is in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

3.1. CHEMISTRY

The final chemistry review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from a chemistry perspective.

The applicant provided ingredient information, including materials for the packaging and container closure system, and mainstream smoke data for the new and predicate products. The amount of (b)(4) increased by 13% and (b)(4) g/g) is present in the new product but not in the predicate product. Furthermore, the base paper weight basis for the new product increased by 25%, roll length increased 40%, and base paper porosity increased 30%. These changes could affect the levels of harmful and potentially harmful constituents (HPHC) produced when the paper is burned. Mainstream smoke data are discussed below.

The container closure system in the new product contains a cardboard holder/display case made of (b)(4) material. The predicate product contains a plastic holder made of polystyrene (b)(4) and is housed in a display case made of (b)(4) The applicant states that cross-contamination between the container closing system and the rolling paper is unlikely to occur. Therefore, the differences in container closure system between the new and predicate products do not cause the new products to raise different questions of public health.

While the paper length increased by 40%, from a chemistry perspective, this increase is not expected to raise concerns, because the rolling paper is cut into sheets, prior to forming the RYO cigarettes. While a 7000 mm roll can produce more cigarettes than a 5000 mm roll, based on the evidence available at this time, a change in tobacco product quantity and size does not cause the new products to raise different questions of public health.

For smoke analysis, the applicant used a third-party lab, who authorized the applicant to reference their Tobacco Product Master File (b)(4) American Spirit RYO tobacco was used to generate mainstream smoke yields for the new and predicate products under the Canadian Intense (CI) smoking regimen. Differences in mainstream smoke yields included the following: TPM (↓13%), nicotine (↓4%), acrolein (↑1%), tar (↓10%), carbon monoxide (↓21%), acetaldehyde (↓19%), crotonaldehyde (↓16%), and formaldehyde (↑31%). A two-one-sided t-test (TOST) statistical analysis was performed comparing the mean values between the new and predicate products. Smoke yields of tar, carbon monoxide, acetaldehyde, crotonaldehyde and formaldehyde were analytically non-equivalent and were deferred to toxicology for further analysis. Because tar, nicotine, and carbon monoxide (TNCO) smoke yields decrease, the addition of calcium carbonate in the new product and the increases in (b)(4), base paper weight basis, and base paper porosity do not cause the new product to raise different questions of public health.

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

3.2. ENGINEERING

The final engineering review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from an engineering perspective.

The rolling papers are sold in one long sheet on a "per roll" basis (7000 mm for the new product and 5000 mm for the predicate product), which is then subdivided at will, by the consumer. Therefore, base paper basis weight is more applicable in this particular case and individual paper mass is not required. The applicant provides identical target specifications and range limits for the new and predicate products for all design parameters except the following: rolling paper base paper porosity (↑ 30%), rolling paper length for the entire roll (↑ 40%), and rolling paper base paper basis weight (↑ 25%). Changes in these design parameters can affect TNCO smoke yields, and these changes were deferred to chemistry.

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

3.3. TOXICOLOGY

The final toxicology review concludes that the new product has different characteristics compared to the predicate product, but the differences do not cause the new product to raise different questions of public health from a toxicology perspective.

The applicant provided HPHC yields of mainstream smoke constituents for the new and predicate products. The formaldehyde yield is higher in the mainstream smoke of the new product compared to the predicate product. However, tar, carbon monoxide (CO), acetaldehyde, and crotonaldehyde are lower in the mainstream smoke of the new product compared to the predicate product, and the new product has a lower puff count compared to the predicate product.

The applicant states that the higher level of formaldehyde in the mainstream smoke of the new product compared to the predicate product is offset by lower levels of acetaldehyde, crotonaldehyde, and tar. Considering the overall analytically nonequivalent higher and lower levels of the totality of HPHC (the nonequivalent higher level of formaldehyde, lower level of tar, lower level of CO, lower level of other volatile organic compounds (VOCs) such as acetaldehyde and crotonaldehyde, and equivalent level of acrolein), the higher level of formaldehyde may not change the overall cancer risk, respiratory or cardiovascular toxicities associated with use of the new product when compared to the predicate product. Furthermore, lower puff count from the new product compared to the predicate product indicates that the user will be exposed to lower levels of HPHC from the new product than from the predicate product.

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

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on April 21, 2021. The FONSI was supported by an environmental assessment prepared by FDA on April 21, 2021.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

Chemistry evaluation complete:

- Container closure system (CCS):
  - New product: cardboard holder in (b)(4) case
  - Predicate product: polystyrene holder in (b)(4) case
- Addition of (b)(4) g/g)
- Increase in (b)(4) (↑13%)
- Tar, nicotine, and carbon monoxide (TNCO) and harmful and potentially harmful chemicals (HPHC) yields (analytically non-equivalent): tar (↓10%), carbon monoxide (↓21%), acetaldehyde (↓19%), crotonaldehyde (↓16%) and formaldehyde (↑31%)

Engineering evaluation complete:

- Increase in rolling paper length of the entire roll (40%)
- Increase in rolling paper base paper basis weight (25%)
- Increase in rolling paper base paper porosity (30%)

Toxicology evaluation complete:

- Increase in formaldehyde in the mainstream smoke (31%)
- Tar, CO, acetaldehyde, and crotonaldehyde in the mainstream smoke are decreased 10, 21, 19, and 16%, respectively
- The puff counts in the TNCO and total aldehydes are lower by 22 and 16%, respectively

I concur with the conclusions of all the scientific reviews that the applicant has demonstrated that these differences in characteristics do not cause the new product to raise different questions of public health as described in Section 3.1-3.3 above. Although there is a difference in the CCS between the new and predicate products, cross-contamination between the CCS and the rolling paper is unlikely to occur and as a result, the CCS is not expected to impact the mainstream smoke yields of HPHCs for the rolling papers in the new and predicate products. Therefore, the difference in the CCS does not cause the new tobacco product to raise different questions of public health. There are increases in rolling paper roll length, rolling paper base paper basis weight, and rolling paper base paper porosity, which may impact TNCO smoke yields. Smoke yields of tar, carbon monoxide, acetaldehyde, crotonaldehyde and formaldehyde were analytically non-equivalent and were deferred to toxicology for further analysis. Because tar, nicotine, and carbon monoxide smoke yields decrease, the addition of (b)(4) in the new product and the increases in (b)(4) base paper weight basis, rolling paper length, and base paper porosity do not cause the new product to raise different questions of public health. Considering the overall nonequivalent higher and lower levels of the totality of HPHCs (the nonequivalent higher level of formaldehyde, lower level of tar, lower level of CO, lower level of other volatile organic compounds (VOCs) such as acetaldehyde and crotonaldehyde, and equivalent level of acrolein), the higher level of formaldehyde may not change the overall cancer risk, respiratory or cardiovascular toxicities associated with use of the new

product when compared to the predicate product. Furthermore, decreased puff count indicates that the user will be exposed to lower levels of HPHCs from the new product. Therefore, the differences in characteristics between the new and predicate product do not cause the new product to raise different questions of public health.

The predicate product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new product is currently in compliance with the FD&C Act. I concur with these reviews and recommend that an SE order letter be issued. FDA examined the environmental effects of finding this new product substantially equivalent and made a finding of no significant impact.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	January 22, 2020	
Receipt date	January 22, 2020	
Applicant	BBK Tobacco & Foods LLP dba HBI International	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International and IBERPAPEL S.L.	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Rolling Paper	
Attributes	**New Product**	**Predicate Product**
STN	**SE0015654**	**N/A**
Product name	JAYS ROLLS SINGLE WIDE[a]	Elements Rolls Ultra Thin SW
Eligibility status	Not applicable	Grandfathered
Package type	Cardboard Holder/Box[b]	Plastic Holder/Box
Package quantity	1 Roll	1 Roll
Characterizing flavor	None	None
Length	7000 mm	5000 mm
Width	37 mm	37 mm
Additional property	Off-white Watermark design: "HBI"	Off-white Watermark design: "HBI"

[a] Brand/sub-brand or other commercial name used in commercial distribution.

[b] Applicant refers to package type as both "booklet" and "holder/box" interchangeably throughout submission. Images in the submission show packaging to be a holder/box.

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Application being amended	Reviewed	Brief Description
February 4, 2020	February 4, 2020	SE0015679	SE0015654	Yes	Response to January 31, 2020 FDA Information Request
September 24, 2020	September 24, 2020	SE0021132	SE0015654	Yes	Response to March 30, 2020 Deficiency Letter