FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	SE0016741, SE0017682, SE0017689, and SE0017790
Common Attributes	
Submission date	June 22, 2020;[1] August 28, 2020;[2] September 2, 2020[3]
Receipt date	June 22, 2020;[1] August 28, 2020;[2] September 2, 2020[3]
Applicant	BBK Tobacco & Foods LLP dba HBI International
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International
Application type	Regular
Product category	Roll-Your-Own Tobacco Products
Product subcategory	Rolling paper; Non-Filtered Cigarette Tube
Cross-Referenced Submissions	
All STNs	(b) (4)
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Addendum to February 24, 2017, Equivalence Testing for SE Evaluations Memo (February 24, 2017 and April 16, 2019)
SE0016741	Memorandum, Use of Surrogate Tobacco Products in SE Reports (September 19, 2016)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Date: 2022.05.11 10:48:18 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief, Division of Product Science
Office of Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.05.12 08:01:30 -04'00'

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

[1] For SE0016741.

[2] For SE0017682 and SE0017689.

[3] For SE0017790.

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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

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review. All STNs cross-referenced a Tobacco Product Master File (TPMF), (b) (4) . A chemistry review was conducted which did not identify any deficiency.

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Kristopher Van Amburg	6/29/2020[4]	Not assigned	N/A
	Riandra Bates	9/11/2020[5]		
	Melanie Proctor	9/11/2020[6]		
Chemistry	DeLauren McCauley	6/16/2021	Theresa Ku	4/11/2022
Engineering	Mary Searing	7/7/2021	Shanker Pershad	4/19/2022
Toxicology	Atinuke Ajiboye	7/10/2021	Atinuke Ajiboye	4/19/2022
Behavioral and clinical pharmacology	Not assigned	N/A	Collin Cunningham	4/11/2022
Environmental science	Vyomesh Patel	4/20/2021	Vyomesh Patel	12/9/2021
TPMF-Chemistry	DeLauren McCauley	3/22/2021	Therese Ku	11/29/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated June 1, 2021,[7] and June 7, 2021,[2] conclude that the evidence submitted by the applicant is adequate

[4] For SE0016741.

[5] For SE0017682 and SE0017689.

[6] For SE0017790.

[7] For SE0016741 and SE0017790.

to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed a review to determine whether the new products are 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 reviews dated May 3, 2022, conclude that the new products are 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 products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a chemistry perspective.

The applicant submitted SE Reports for roll-your-own (RYO) rolling paper, paper tip, non-filtered cigarette tube/filtered cigarette tube, and non-filtered cigarette tube, ingredients other than tobacco, co-packaging materials, container closure system (CCS), and mainstream smoke data for the new and corresponding predicate products. The ingredients are either the same or similar between the new and predicate products. The applicant provided testing data for a wide range of HPHCs (i.e., tar, nicotine, CO [TNCO], carbonyls, volatiles, phenols, and PAHs) under the Canadian Intense (CI) smoking regimen for SE0017682, SE0017689, and SE0017790 in the original submission. The chemistry review determined that the testing method information was sufficient. The chemistry review also determined that these HPHC yields in the new products are either analytically equivalent or analytically nonequivalent, but decreased. These changes do not raise concerns from a chemistry perspective.

For SE0016741, the reported difference in paper porosity (↓10%, 0.8 CU) between the new and predicate products may impact mainstream smoke yields and this issue was deferred to chemistry by engineering. In response to the deficiency letter, the applicant provided TNCO yields using surrogate new and predicate products, which have different dimensions than their respective new and predicate products. The chemistry review determined that such surrogate products are acceptable because these dimensional changes are proportional and therefore, are not expected to impact the relative percent differences in mainstream smoke yields between the new and predicate products. All mainstream smoke yields between the surrogate, new, and predicate products in SE0016741 are analytically equivalent. The methodology and validation data are referenced in TPMF, (b) (4) , and contains sufficient information from a chemistry perspective (see chemistry TPMF review completed by Therese Ku on November 29, 2021). Therefore, the paper porosity difference between the new and predicate products in SE0016741 does not cause the new product to raise different questions of public health, from a chemistry perspective.

Additionally, for SE0017682, the testing result showed a 21% decrease in nicotine yield in the new product, which may impact user behavior. The applicant provided scientific justification to support the new and predicate products by stating that lower nicotine does not lead to

compensation and increased initiation. However, the differences in nicotine were deferred to Behavioral and Clinical Pharmacology (BCP) for further evaluation of impact on user behaviors.

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

3.2. ENGINEERING

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

For SE0017790, there are no differences in cigarette paper watermarked paper porosity target specifications and range limits between the new and predicate products. For SE0016741, SE0017682 and SE0017689, there are some differences in the watermarked paper porosity measured average values, which were deferred to chemistry for the evaluation of TNCO.

In SE0017682 and SE0017689, the new product tube mass increases 9% – 83% compared to the corresponding predicate product. Differences in cigarette tube mass may affect the amount of tobacco that is burned, and in turn, affect smoke constituent yields, however, these were deferred to chemistry for the evaluation of TNCO. The applicant also provides new product target specifications and range limits but without test data for paper tip inner radius, paper tip outer radius, paper tip angle, and paper tip length for SE0017682 and SE0017689. These parameters target specification increases 54% – 138% or decreases 19% – 55% compared to the corresponding predicate product. Differences in these design parameters may affect the amount of tobacco that is burned, and in turn, affect smoke constituent yields, however, these were deferred to chemistry for the evaluation of TNCO.

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

3.3. TOXICOLOGY

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

The applicant provided testing data for a wide range of HPHCs (i.e., tar, nicotine, CO [TNCO], carbonyls, volatiles, phenols, and PAHs) under the Canadian Intense (CI) smoking regimen for SE0017682, SE0017689, and SE0017790, which were reviewed in the 1st round toxicology review. These HPHC yields in the new products are either analytically equivalent or analytically nonequivalent, but decreased. These changes do not raise concerns from a toxicology perspective.

In SE0016741, the applicant reported a substantially lower measured porosity of the watermarked new product compared to the watermarked predicate product (↓10%, 0.8 CU), which may lead to higher mainstream smoke yields of harmful and potentially harmful constituents (HPHCs). To address this issue, the applicant provided TNCO yields under CI smoking regimen for two surrogate products, which are acceptable according to the chemistry review. The TNCO yields are analytically equivalent between the surrogate new and predicate products. Therefore, the difference in air permeability between the new and predicate products does not cause the new product to raise different questions of public health from a toxicological perspective.

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

3.4. BEHAVIORAL AND CLINICAL PHARMACOLOGY

The behavioral and clinical pharmacology review concludes that the new products have different characteristics compared to the corresponding predicate products, but the differences do not cause the new products to raise different questions of public health from a behavioral and clinical pharmacology perspective.

While in SE0016782 there was a lower nicotine yield from the new product compared to the predicate product, the applicant adequately addressed concerns by providing an explanation for possible differences in nicotine found by smoking machines and the relevance of such data to a product that is packed and finished by the consumer. The applicant also provided literature that suggests that a) relatively small differences in nicotine, such as those observed between the new and predicate products, are unlikely to result in compensatory smoking behaviors and b) addressing the possibility of increased initiation in youth due to decreased nicotine yield. The data supports that the observed lower nicotine yield between the new and predicate product was considerably smaller than those at which compensatory smoking have been observed. Available evidence suggests it is unlikely that in this case, the decrease in nicotine yield in the new product would have an increased effect on youth progression to regular use compared to the predicate product.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health from a behavioral and clinical pharmacology perspective.

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on April 25, 2022. The FONSI was supported by an environmental assessment prepared by FDA on April 26, 2022.

5. CONCLUSION AND RECOMMENDATION

The new and the predicate products have the following characteristics:

- SE0016741
    - watermarked rolling paper cigarette paper porositydecreases 10%
- SE0017682
    - Nicotine decreases 21% in new product
- SE0017689
    - tube length decreases 8% in new product
- SE0017682 and SE0017689
    - RYO non-filtered cigarette tube cigarette paper porosity for watermarked paper
        - decreases 62% in new products
    - RYO non-filtered cigarette tube
        - Tube large diameter decreases 43 – 55% in new products
        - Tube small diameter decreases 45% in new products
        - Tube mass increases 9 – 83% in new products
    - RYO tube paper tip
        - Inner radius increases 138% and decreases 28%, respectively in new products
        - Outer radius increases 117% and decreases 25%, respectively in new products
        - Angle decreases 45% and increases 76%, respectively in new products
        - Length increases 54% and decreases 19%, respectively in new products

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 products to raise different questions of public health as described in Section 3.1 – 3.4 above. In all of the SE Reports, the ingredients are either the same or similar between the new and predicate products. However, there are some differences in design parameters such as paper porosity, tube mass, tube diameter and length. These changes could be of concern because they could impact smoke chemistry. However, the measured HPHC yields including TNCO yields are either analytically equivalent or decreased, which do not raise concerns from a chemistry or toxicology perspective. In SE0017682, nicotine yield decreases 21% in the new product, which could impact user behaviror. BCP review concludes that in this case, the decreased nicotine yield is unlikely to cause compensatory smoking or increased effect on youth progression to regular use of the new product. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new products to raise different questions of public health.

The predicate products meet statutory requirements because they were determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

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

6. APPENDICES

Appendix A. New and predicate products[8]

Common Attributes		
Applicant	BBK Tobacco & Foods LLP dba HBI International	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Attributes	**New Product**	**Predicate Product**
STN	**SE0016741**	**N/A**
Product name	RAW ORGANIC HEMP 1 ¼	ELEMENTS 1 ¼[9]
Submission date	June 22, 2020	Not Applicable
Receipt date	June 22, 2020	Not Applicable
Product subcategory	Rolling Paper	Rolling Paper
Eligibility status	Not Applicable	Grandfathered
Package type	Booklet	Booklet
Package quantity	50 Papers	50 Papers
Characterizing flavor	None	None
Length	76 mm	76 mm
Width	44 mm	44 mm
Additional property	Off-white color "RAW" watermark	White color "HBI" watermark
Attributes	**New Product**	**Predicate Product**
STN	**SE0017682**	**N/A**
Product name	RAW PRE-ROLLED CONE LEAN 20 PACK	TORPEDOES PRE ROLLED CONE PAPERS
Submission date	August 28, 2020	Not Applicable
Receipt date	August 28, 2020	Not Applicable
Product subcategory	Non-Filtered Cigarette Tube	Non-Filtered Cigarette Tube
Eligibility status	Not Applicable	Grandfathered
Package type	Cardboard Box	Plastic Container
Package quantity	20 Tubes	3 Tubes
Characterizing flavor	None	None
Length	109 mm	106 mm
Diameter	9 mm	20 mm
Additional property	Off-white color "RAW" watermark	White color "cones" watermark

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

[9] Also marketed as ELEMENTS ULTRA RICE PAPER 1 ¼ BOX25 MP.

Attributes	New Product	Predicate Product
STN	**SE0017689**	**N/A**
Product name	RAW PRE-ROLLED CONE 98 SPECIAL 20 PACK	TORPEDOES PRE ROLLED CONE PAPERS
Submission date	August 28, 2020	Not Applicable
Receipt date	August 28, 2020	Not Applicable
Product subcategory	Non-Filtered Cigarette Tube	Non-Filtered Cigarette Tube
Eligibility status	Not Applicable	Grandfathered
Package type	Cardboard Box	Plastic Container
Package quantity	20 Tubes	3 Tubes
Characterizing flavor	None	None
Length	98 mm	106 mm
Diameter	11.5 mm	20 mm
Additional property	Off-white color "RAW" watermark	White color "cones" watermark
Attributes	**New Product**	**Predicate Product**
STN	**SE0017790**	**N/A**
Product name	RAW SW DF (DOUBLE FEED)	ELEMENTS SW
Submission date	September 2, 2020	Not Applicable
Receipt date	September 2, 2020	Not Applicable
Product subcategory	Rolling Paper	Rolling Paper
Eligibility status	Not applicable	Grandfathered
Package type	Booklet	Booklet
Package quantity	100 Papers	100 Papers
Characterizing flavor	None	None
Length	70 mm	70 mm
Width	37 mm	37 mm
Additional property	Off-white color "RAW" watermark	White color "HBI" watermark

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
May 20, 2021	May 20, 2021	SE0024631	SE0016741	Yes	Response to grandfather information request.
October 7, 2021	October 7, 2021	SE0025017	SE0016741, SE0017682, SE0017689, SE0017790	Yes	Response to July 21, 2021, Deficiency letter