

Technical Project Lead (TPL) Review of SE Reports

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	SE0016550, SE0016572, SE0017543
Common Attributes	
Submission date	April 30, 2020 ¹ or August 25, 2020 ²
Receipt date	April 30, 2020 ¹ or August 25, 2020 ²
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	Paper Tip
Cross-Referenced Submissions	
All new tobacco products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new tobacco products	None
Recommendation	
Issue Substantially Equivalent (SE) order(s) for the new tobacco product(s) subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Gloria J. Kulesa -S
Date: 2020.12.03 11:44:27 -05'00'

Gloria Kulesa
Engineering Branch Chief, Division of Product Science
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.12.03 13:40:50 -05'00'

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

¹ SE0016550 and SE0016572

² SE0017543

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1. BACKGROUND

1.1. NEW AND PREDICATE TOBACCO PRODUCTS

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

1.2. REGULATORY ACTIVITY

See Appendices for tobacco products and amendments. FDA received three SE Reports from BBK Tobacco & Foods LLP dba HBI International: SE0016550 and SE0016572 on April 30, 2020 and SE0017543 on August 25, 2020. FDA subsequently issued acceptance letters on May 14, 2020 and September 14, 2020. On September 24, 2020, BBK Tobacco & Foods LLP dba HBI International submitted a response to an email request for information from the Office of Compliance and Enforcement (OCE) for SE0016550.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

STNs	Discipline	Cycle 1: Reviewer(s)	Review Date
SE0016550 and SE0016572	Regulatory	Michael Jokoh	5/15/2020
SE0017543	Regulatory	Kimberly Jordan	9/14/2020
SE0016550, SE0016572, SE0017543	Chemistry	Salome Bhagan	11/4/2020 ³
SE0016550, SE0016572, SE0017543	Engineering	Robert Borthwick	10/30/2020 ⁴
SE0016550, SE0016572, SE0017543	Toxicology	Shannon Dunn	10/29/2020
SE0016550, SE0016572, SE0017543	Environmental Science	Gerome Burke	11/5/2020

2. COMPLIANCE REVIEW

For SE0016550 and SE0016572, OCE completed a review to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated October 8, 2020, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products in SE0016550 and SE0016572 are grandfathered and, therefore, are eligible predicate tobacco products.

³ Addendum review was completed on 11/16/2020

⁴ Addendum review was completed on 11/17/2020

The predicate tobacco product in SE0017543 was determined to be substantially equivalent by FDA under SE0015554. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

OCE also completed reviews to determine whether the new tobacco 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 November 20, 2020, conclude that the new tobacco 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 chemistry review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

The new tobacco products in SE0016550 and SE0016572 have an 18% increase in (b) (4), 17% decrease in (b) (4) and 33% decrease in (b) (4) compared to the corresponding predicate tobacco products. The new tobacco product in SE0017543 has an 18% increase in (b) (4), 67% increase in (b) (4) and 67% decrease in (b) (4) compared to the predicate tobacco product. Because the new tobacco products (paper tips) are not combusted and do not provide any filtration for the smoke, the ingredient changes do not affect the smoke chemistry and do not cause the new tobacco products to raise different questions of public health. The applicant did not provide any harmful and potentially harmful constituents (HPHCs) data in any of the SE Reports or ink ingredients data for SE0017543. Since the new tobacco products do not contain tobacco, do not provide any filtration for the smoke, and are not combusted, HPHC information is not needed. In addition, the ink is covered by the rolling paper; there is no contact between the ink and the user's mouth. Because the ink is not in contact with the user and the pre-rolled paper tip is not combusted or otherwise impact smoke chemistry, the ink changes to the pre-rolled paper tip of the new tobacco product compared to the predicate tobacco product in SE0017543 do not cause the new tobacco product to raise different questions of public health. The chemistry analysis on package quantity changes was confusing. As TPL, I am adding a clarification to the chemist's analysis. Based on the currently available scientific evidence regarding consumer perception and use, FDA has concluded that at this time, a change in product quantity does not cause new tobacco products to raise different questions of public health.

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

3.2. ENGINEERING

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from an engineering perspective.

3.3. TOXICOLOGY

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

(b) (4) is present in the paper of the cone tip and has increased 18% per gram of paper in SE0016550, SE0016572, and SE0017543. The tip will not be burned. (b) (4) is not considered a toxic chemical and is generally recognized as safe. Therefore, the increase in the levels of (b) (4) is not a toxicological concern and does not cause the new tobacco products to raise different questions of public health from a toxicology perspective. The chemistry reviewer deferred to toxicology the review of the change made to the storage of the new tobacco product in SE0017543. The new tobacco product is stored in a steel coated tin and the predicate tobacco product was packaged in a cellulose based cardboard. Even though the new tobacco product is in direct contact with the steel coated tin, toxicology finds that the packaging material for the new tobacco product in SE0017543 is not a toxicological concern and does not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products 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 November 20, 2020. The FONSI was supported by an environmental assessment prepared by FDA on November 20, 2020.

5. CONCLUSION AND RECOMMENDATION

The new and corresponding predicate tobacco products have the following characteristics:

- SE0016550 and SE0016572:
 - 18% increase in (b) (4), 17% decrease in (b) (4) and a 33% decrease in (b) (4)
- SE0017543:
 - 18% increase in (b) (4), 67% increase in (b) (4) and a 67% decrease in (b) (4)
 - The blue ink "ELEMENTS" marking is changed to red "RAW"
 - Change in packaging material from cellulose-based cardboard in the predicate tobacco product to a steel coated tin for the new tobacco product.
 - The package quantity increases from 21 to 100 pre-rolled tips per pack

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 tobacco products to raise different questions of public health as described in Sections 3.1-3.3 above. The non-rolled paper tips in SE0016550 and SE0016572 and the pre-rolled paper tips in SE0017543 are not combusted components and do not provide any filtration for the smoke. Therefore, the ingredient changes in the new tobacco products do not affect the smoke chemistry. For SE0017543, the ink is not in contact with the user, the packaging material change does not have a toxicological concern, and the quantity change does not cause the new tobacco products to raise different questions of public health.

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

The predicate tobacco products in SE0016550 and SE0016572 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The predicate tobacco product in SE0017543 was previously determined to be substantially equivalent by FDA under SE0015554, as identified on the cover page of this review. Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act). No differences in characteristics between the new tobacco product and the product commercially marketed in the United States as of February 15, 2007, raise different questions of public health.

For SE0017543, comparison of the new tobacco product to the grandfathered tobacco product reveals that the new tobacco product has the following differences in characteristics:

- 18% increase in (b) (4)
- 67% increase in (b) (4)
- 67% decrease in (b) (4)
- Red ink "RAW" marking added
- Steel coated tin packaging for the new tobacco product and cellulose-based cardboard booklet in the grandfathered tobacco product
- Increase in package quantity from 50 to 100 pre-rolled tips per pack

The packaging material change and the decreases in ingredients in the new and predicate tobacco product are the same as in the new and grandfathered tobacco product. The product quantity change does not cause the new tobacco products to raise different questions of public health. The new tobacco products include a red ink "RAW" marking while the grandfathered tobacco products do not have a marking. The ink is covered by the rolling paper so there is no contact between the ink and the user's mouth. Therefore, the differences in characteristics between the new and grandfathered tobacco products do not cause the new tobacco product to raise different questions of public health.

The new tobacco 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 tobacco products substantially equivalent and made a finding of no significant impact.

6. APPENDICES

Appendix A. New and predicate tobacco products

Common Attributes		
Submission date	April 30, 2020 ¹ or August 25, 2020 ²	
Receipt date	April 30, 2020 ¹ or August 25, 2020 ²	
Applicant	BBK Tobacco & Foods LLP dba HBI International	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Paper Tip	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016550	N/A
Product name	RAW ORGANIC HEMP CONNOISSEUR KSS (with tips)	ELEMENTS KS SLIM with FILTER TIPS
Eligibility status	Not applicable	Grandfathered
Package type	Book	Booklet
Package quantity	32 Tips	32 Tips
Characterizing flavor	None	None
Length	54 mm	54 mm
Width	19 mm	19 mm
Additional property	Tips only	The paper is off-white in color and has "ELEMENTS" watermark
STN	SE0016572	N/A
Product name	RAW ORGANIC HEMP ARTESANO KSS	ELEMENTS KS SLIM with FILTER TIPS
Eligibility status	Not applicable	Grandfathered
Package type	Book	Booklet
Package quantity	32 Tips	32 Tips
Characterizing flavor	None	None
Length	54 mm	54 mm
Width	19 mm	19 mm
Additional properties	5 perforations Tips only	The paper is off-white in color and has "ELEMENTS" watermark

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0017543	SE0015554
Product name	RAW PRE-ROLLED 100 TIP TIN	ELEMENTS PRE-ROLLED TIPS
Product Subcategory	Paper Tip	Paper Tip
Eligibility status	Not applicable	Previously Found SE
Package type	Tin	Tray Slider Box
Package quantity	100 Tips	21 Tips
Characterizing flavor	None	None
Length	58.5 mm	58.0mm
Width	18 mm	18 mm
Additional properties	Beige Red "RAW" logo Perforations Pre-rolled	White Blue "ELEMENTS" logo Pre-rolled

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
September 24, 2020	September 24, 2020	SE0021131	SE0016550	Yes	Active	Correction or clarification to name of new tobacco product for SE0016550 in cover letter of original submission in response to CTP OCE inquiry.