

**Technical Project Lead (TPL) Review:
SE0002390 and SE0002393**

SE0002390: RAW Organic SW Double	
Package Type	Booklet
Package Quantity	100 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Properties	Each package contains 25 booklets composed of 100 sheets per booklet
SE0002393: RAW SW SW	
Package Type	Booklet
Package Quantity	50 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Additional Properties	Each package contains 25 booklets composed of 50 sheets per booklet
Administrative Attributes of SE Reports	
Applicant	BBK Tobacco & Foods LLP dba HBI International ¹
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) orders.	

¹ The applicant was previously known as "HBI International, a BBK Tobacco & Foods, LLP Company." In a telecon dated August 11, 2016, the applicant clarified that they would like to be identified as "BBK Tobacco & Foods dba HBI International."

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.10.03 10:38:10 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy 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 Matthew R. Holman -S
Date: 2017.10.03 10:41:26 -04'00'

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 products:

SE0002390: RAW Organic SW Double	
Product Name	RAW 1 and ¼ Box 24
Package Type	Booklet
Package Quantity	32 sheets
Length	76 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Each package contains 24 booklets composed of 32 sheets per booklet
SE0002393: RAW SW SW	
Product Name	RAW 1 and ¼ Box 24
Package Type	Booklet
Package Quantity	32 sheets
Length	76 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Each package contains 24 booklets composed of 32 sheets per booklet

The predicate tobacco products are roll-your-own (RYO) rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 21, 2011, the applicant submitted these SE Reports. FDA issued Acknowledgement letters on September 26, 2011. FDA issued Advice/Information Request letters (A/I letters) on December 19, 2012. In response, the applicant submitted amendments, SE0006879 and SE0006882, on January 18, 2013 for SE0002390 and SE0002393, respectively. In response to FDA's December 19, 2012 A/I letters, the applicant states the dates the new products were first introduced or delivered for introduction into interstate commerce for commercial distribution in the US were on August 21, 2012 and August 10, 2011 for SE0002390 and SE0002393, respectively. Therefore, the SE reports are classified as regular SE Reports.

The applicant submitted a solicited amendment for SE0002393 on April 3, 2013 (SE0008195) with product identification information for the new tobacco product. On

April 4, 2014, FDA issued a Notification letter, indicating that scientific review was expected to begin on May 20, 2014. On April 16, 2014, April 24, 2014, May 1, 2014, and May 29, 2014, the applicant submitted solicited amendments (SE0010407, SE0010455, SE0010465, and SE0010513, respectively) with product identification information for the new and predicate tobacco products. FDA issued an A/I letter on January 5, 2016. In response, the applicant submitted an amendment on March 1, 2016 (SE0012991). On May 25, 2016, FDA issued a Preliminary Finding letter (PFind letter). In response, the applicant submitted an amendment on June 21, 2016 (SE0013438). On December 29, 2016, December 30, 2016, January 23, 2017, and May 11, 2017, the applicant submitted unsolicited amendments (SE0013809, SE0013810, SE0013840, and SE0014085, respectively) to correct errors in previous amendments, after all scientific reviews were completed with the exception of the environmental science review. Although we generally do not review unsolicited amendments after scientific review has concluded, the technical project lead (TPL) for these SE Reports conducted a cursory review of the unsolicited amendments (SE0013809, SE0013810, SE0013840, SE0014085) which do not alter the conclusions of the previously finalized chemistry, engineering, or toxicology reviews or this TPL review. However, an addendum was necessary for the social science review due to updated paper dimensions and the number of booklets per package. On June 8, 2017, FDA issued a PFind letter. In response, the applicant submitted an amendment on July 5, 2017 (SE0014191).

Product Name	SE Report	Amendments
RAW Organic SW Double	SE0002390	SE0006879 SE0010407 SE0010455 SE0010465 SE0010513 SE0012991 SE0013438 SE0013809 SE0013810 SE0013840 SE0014085 SE0014191
RAW SW SW	SE0002393	SE0006882 SE0008195 SE0010407 SE0010455 SE0010465 SE0010513 SE0012991 SE0013438 SE0013809 SE0013810

		SE0013840 SE0014191
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1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Gregory Bissonette on September 30, 2011, Marcella White on December 19, 2012 and June 13, 2013, and Ebony Jackson on October 4, 2016.

The final reviews conclude that the SE Reports are 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 grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE review dated June 6, 2014, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.²

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 reviews dated November 1, 2016, August 21, 2017, and October 02, 2017 conclude 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 Changyu Chae on September 12, 2014 and Kimberly Agnew-Heard on April 11, 2016 and July 29, 2016.

² An addendum to the June 6, 2014 OCE review was completed on July 3, 2017 to correct the unique identification of the predicate products.

The final 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 review identifies the following differences:

- Lower ingredient quantities (because of smaller paper dimensions)
- Decreased TNCO³ yields under Canadian Intense smoking regimen
- Decreased carbonyl⁴ yields under Canadian Intense smoking regimen

Based on decreased TNCO and carbonyl yields when tobacco filler was added to the rolling papers, the review concludes that these 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.

4.2. ENGINEERING

Engineering reviews were completed by Christopher Brown on September 12, 2014 and by Erdit Gremi on April 12, 2016 and August 12, 2016.

The final engineering review concludes that the new tobacco products have different characteristics related to product design compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The review identifies the following differences related to product design:

- 8% decrease in paper length⁵
- 16% decrease in paper width⁵
- 22-27% decrease in paper mass
- 18% increase in base paper basis weight⁶
- 30% increase in base paper porosity⁶

The applicant added tobacco filler to the rolling papers and measured TNCO yields under the Canadian Intense smoking regimen. TNCO yields were decreased in the new tobacco products compared to the corresponding predicate tobacco products. Therefore, the review concludes that the differences in characteristics between the new and corresponding predicate tobacco products

³ Tar, nicotine, and carbon monoxide

⁴ Acetaldehyde, acrolein, and formaldehyde

⁵ While the final engineering review indicates that these changes apply to both SE0002390 and SE0002393, the applicant provided an unsolicited amendment which corrected some information and these changes only apply to SE0002390. I conclude from my review of this unsolicited amendment that the corrected information does not cause the new tobacco product to raise different questions of public health.

⁶ SE0002390 only

do not cause the new tobacco products to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Brian Erkkila on December 3, 2015, and by Mayo Wright on April 26, 2016 and August 18, 2016.

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

- Decreased TNCO yields under Canadian Intense smoking regimen
- Decreased carbonyl yields under Canadian Intense smoking regimen

Based on the decreased TNCO and carbonyl yields when tobacco filler was added to the rolling papers, these reductions in HPHC yields result in a change in product toxicology for these SE Reports and however, the review concludes that 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.

4.4. SOCIAL SCIENCE

A social science review was completed by David Portnoy on September 22, 2014.

The social science review concludes that the characteristics are different for the new and corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health with respect to consumer perception and use. The review identifies the following differences:

- 8% decrease in paper length⁷
- 41% increase in paper width⁶
- 16% decrease in paper width⁷
- 4% increase in the number of booklets per package⁶
- 108% increase in the number of booklets per package⁷
- Changes in booklet package dimensions

The review did not identify the following difference between the new and corresponding predicate tobacco products as the review was completed in

⁷ SE0002393 only

September 2014 and the number of sheets per booklet was submitted in the June and December 2016 amendments (SE0013438, SE0013809, SE0013810):

- 56-213% increase in number of sheets per booklet

As to the differences in paper dimensions and the number of booklets per package between the new and corresponding predicate tobacco products, as explained in the September 2014 review, in the context of rolling papers, there is limited available evidence on the impact of these differences on consumer perception and use. However, given the small magnitude of these changes (e.g., minor difference in the number of booklets per package (a change from 24 to 25 per package)), the review concludes that these differences do not cause the new tobacco products to raise different questions of public health. Therefore, the review concludes that these differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

As to the difference in booklet package dimensions between the new and corresponding predicate tobacco products, although the booklet is a component or part of the tobacco product, to the extent the review evaluated the impact of this difference on consumer perception and use, I do not believe that such review is warranted in this instance. Where packaging is a component or part of a tobacco product, changes to it may be relevant in assessing the appeal of the product to consumers. However, that is not the case here—the review’s analysis was based on the change in dimensions of the package and how that change, by itself, might affect consumer perception of the product. The review did not identify any changes to the product’s performance, composition, constituents, or characteristics that could impact the appeal of the product.

The applicant submitted the amendments to the SE Reports (SE0012991, SE0013438, SE0013809, SE0013810 and SE0014191) which contain a series of revised parameters for the product length, width, number of sheets per booklet, and number of booklets per package. The September 28, 2017, addendum to the social science review clarifies that these revised parameters do not change the conclusions noted in the September 22, 2014 Social Science review.

Therefore, the differences in paper length, width, number of booklets per package and number of sheets per booklet between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Christine Modovsky on May 16, 2017.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 29, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 29, 2017.

6. CONCLUSION AND RECOMMENDATION

The following are the differences in characteristics between the new and predicate tobacco products⁸:

- Lower ingredient quantities (because of smaller paper dimensions)
- Decreased TNCO yields under Canadian Intense smoking regimen
- Decreased carbonyl yields under Canadian Intense smoking regimen
- 22-27% decrease in paper mass
- 18% increase in base paper basis weight⁶
- 30% increase in base paper porosity⁶
- 16% decrease in paper width
- 8% decrease in paper length
- 4% increase in the number of booklets per package⁶
- 108% increase in the number of booklets per package⁷
- 56-213% increase in number of sheets per booklet
- Changes in booklet package dimensions

The reviews conclude that these differences in characteristics do not cause the new tobacco products to 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 products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. 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.

SE order letters should be issued for the new tobacco products in SE0002390 and SE0002393, as identified on the cover page of this review.

⁸ Differences in characteristics based on the third cycle chemistry review, third cycle engineering review, third cycle toxicology review, first cycle social science review and addendum to the first cycle social science review.