

Technical Project Lead (TPL) Review: SE0013974-SE0013976

SE0013974: OCB XPERT Blue	
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0013975: OCB XPERT Double	
Package Type	Booklet
Package Quantity	100 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0013976: OCB XPERT XXL	
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Cigarette Rolling Papers
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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Date: 2018.02.02 13:23:08 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2018.02.02 13:37:26 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the same predicate tobacco product for each SE Report:

SE0013974: OCB XPERT Blue	
SE0013975: OCB XPERT Double	
SE0013976: OCB XPERT XXL	
Product Name	JOB Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 14, 2017, FDA received three SE Reports from Republic Tobacco, LP. FDA issued an Acknowledgement letter to the applicant on March 21, 2017. FDA issued a scientific Advice and Information letter on June 7, 2017. The applicant submitted a response (SE0014219) on July 28, 2017. FDA issued a Preliminary Finding (Pfind) letter on October 20, 2017. The applicant submitted a response (SE0014397) on November 6, 2017.

Product Name	SE Report	Amendments
OCB XPERT Blue	SE0013974	SE0014219 SE0014397
OCB XPERT Double	SE0013975	
OCB XPERT XXL	SE0013976	

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

An acceptance review was completed by William Spears on March 21, 2017.

The final review concludes 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 product in SE0013974, SE0013975, and SE0013976 (JOB Tribal King Size) is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated April 21, 2017, 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 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 review dated January 22, 2018, concludes 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 Stephanie Daniels on May 10, 2017, and September 14, 2017, and by Salome Bhagan on December 26, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the predicate tobacco product but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The reviews identified the following differences related to product composition:

- The new tobacco products contain cellulose derived from (b) (4) while the predicate tobacco product contains cellulose derived from (b) (4)
- The new tobacco products in SE0013974 and SE0013975 have a (b) (4) decrease in cellulose (b) (4), which corresponds with a decrease in paper size
- The new tobacco product in SE0013976 has a (b) (4) increase in cellulose (b) (4)
- The new tobacco products have a (b) (4) (SE0013974 and SE0013975) or (b) (4) (SE0013976) increase in (b) (4)
- The new tobacco products in SE0013974 and SE0013975 have a (b) (4) decrease in (b) (4)
- The new tobacco products have a (b) (4) (SE0013974 and SE0013975) or (b) (4) (SE0013976) increase in (b) (4)
- The adhesive ingredient (b) (4) is added to the new tobacco products
- The new tobacco products have a (b) (4) decrease in (b) (4)
- The new tobacco products in SE0013974 and SE0013975 have a (b) (4) decrease in (b) (4)

Although the new and predicate tobacco products are cigarette rolling papers that contain no tobacco, pyrolysis of starch and (b) (4) can impact the smoke chemistry of rolling papers. To address the changes in ingredients, including the increase in (b) (4) and (b) (4), the

applicant submitted HPHC data (acetaldehyde, formaldehyde, acrolein, and benzene) generated from test cigarettes made using the new and predicate tobacco products and the same commercial tobacco filler. Per test cigarette, each HPHC tested was decreased or marginally increased in the new tobacco products compared to the predicate tobacco product. Furthermore, although the percent change for (b) (4) and (b) (4) is relatively large, the (b) (4) comprises (b) (4) and (b) (4) less than (b) (4) of the total paper weight. Therefore, the 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 chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Tiffany Petty on May 11, 2017, and by Yan Sun on September 8, 2017.

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

- 1150% increase in base paper porosity
- 4% increase in base paper basis weight
- 46% decrease in paper mass (SE0013974 and SE0013975)
- 3% increase in paper mass (SE0013976)
- 37% decrease in length and 18% decrease in width (SE0013974 and SE0013975)

The applicant provided all of the target specifications, upper and lower range limits, and test data for the applicable design parameters. The engineering review found that given the likelihood that the increase in base paper porosity reduces the tar yields and the amount of tobacco consumed during a single puff, that difference does not cause the new tobacco products to raise different questions of public health. As noted in the chemistry review, the applicant submitted tar yields, which were lower in the new tobacco products by (b) (4) (SE0013974), (b) (4) (SE0013975), or increased by (b) (4) (SE0013976), which falls within the error of the method used. Consequently, the increase in base paper porosity does not cause the new tobacco products to raise different questions of public health. Both the differences in base paper basis weight (all products) and paper mass (SE0013976) were minor, and these differences do not cause the new tobacco products to raise different questions of public health. Given the likelihood that the decrease in paper mass (SE0013974 and SE0013975) results in a decrease in smoke constituent yields, these differences do not cause the new tobacco products to raise different questions of public health. Given the likelihood that a decrease in paper length and width does not adversely affect smoke constituent yields and reduces the amount of tobacco available to be burned, these differences do not cause the new tobacco products to raise different questions of public health. Test data submitted by the applicant show that smoke constituent yields are not adversely affected by the changes in physical parameters. As noted in the chemistry review, the yields of several HPHCs in mainstream smoke are reduced in the new tobacco products in SE0013974 and SE0013975 by as much as (b) (4). Therefore, the 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 an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Mayo J. Wright on May 15, 2017, and September 13, 2017.

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

- The new tobacco product in SE0013976 has a (b) (4) increase in cellulose (b) (4)
- The new tobacco products have a (b) (4) (SE0013974 and SE0013975) or (b) (4) (SE0013976) increase in (b) (4)
- The new tobacco products have a (b) (4) (SE0013974 and SE0013975) or (b) (4) (SE0013976) increase in (b) (4)
- The adhesive ingredient (b) (4) is added to the new tobacco products

The higher levels of cellulose, (b) (4), and (b) (4) in the new tobacco products may increase smoke yields of carbon monoxide. The applicant provided carbon monoxide yields for the new and predicate tobacco products. The mean carbon monoxide yields from the new tobacco products in SE0013974, SE0013975, and SE0013976 were decreased (b) (4) (b) (4) respectively) when compared to the predicate tobacco product. (b) (4)

(b) (4) which can undergo pyrolysis when burned to form HPHCs (e.g., acetaldehyde and formaldehyde). The applicant submitted smoke yields of acetaldehyde and formaldehyde for the new and predicate tobacco products. The acetaldehyde and formaldehyde yields of the new tobacco products did not increase significantly compared to the predicate tobacco product, so the addition of (b) (4) does not cause the new tobacco products 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 products to raise different questions of public health related to toxicology.

4.4. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on May 8, 2017.

The social science review did not identify any differences in characteristics between the new and predicate tobacco products in SE0013976 that could cause the new tobacco product to raise different questions of public health; therefore, the differences between the new and predicate tobacco products in SE0013976 do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review concludes that the characteristics are different for the new and predicate tobacco products in SE0013974 and SE0013975, but the differences do not cause the new tobacco products to raise different

questions of public health from a social science perspective. The review identified the following differences:

- 56% increase in package quantity (32 to 50 papers) for SE0013974
- 213% increase in package quantity (32 to 100 papers) for SE0013975
- 37% decrease in product length (109 to 69 mm) for SE0013974 and SE0013975
- 18% decrease in product width (44 to 36 mm) for SE0013974 and SE0013975

The social science review states that currently, FDA is not aware of any research that provides scientific evidence for the relationship between the package quantity, product length or width of a RYO tobacco product and consumer use. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products in SE0013974 and SE0013975 to raise different questions of public health from a social science perspective.

To clarify the social science review, I find that there is no available scientific evidence on the influence differences in package quantity, product length, or product width has on consumer perceptions of harm or use intentions to indicate that these differences could cause the new tobacco products to raise different questions of public health from a social science perspective. Moreover, the Office of Science (OS) prepared a memorandum¹ summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco products in SE001394 and SE0013975 to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 2, 2018. The FONSI was supported by an environmental assessment prepared by FDA on February 2, 2018.

6. CONCLUSION AND RECOMMENDATION

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

SE0013974 and SE0013975

- The new tobacco products contain cellulose derived from (b) (4) while the predicate tobacco product contains cellulose derived from (b) (4)
- The new tobacco products have a (b) (4) decrease in cellulose (b) (4)
- The new tobacco products have an (b) (4) decrease in (b) (4)
- The ingredient (b) (4) is added to the new tobacco products
- The new tobacco products have a (b) (4) increase in (b) (4)
- The new tobacco products have a (b) (4) increase in (b) (4)
- The new tobacco products have a (b) (4) decrease in (b) (4)

¹ See memorandum on product quantity changes, dated December 7, 2017.

- The new tobacco products have a (b) (4) decrease in (b) (4)
- The new tobacco products have a 56% (SE0013974) or 213% (SE0013975) increase in package quantity
- The new tobacco products have a 46% decrease in rolling paper mass
- The new tobacco products have a 4% increase in base paper basis weight
- The new tobacco products have a 1150% increase in base paper porosity
- The new tobacco products have a 37% decrease in length (109 to 69 mm)
- The new tobacco products have an 18% decrease in width (44 to 36 mm)

SE0013976

- The new tobacco product contains cellulose derived from (b) (4) while the predicate tobacco product contains cellulose derived from (b) (4)
- The new tobacco product has a (b) (4) increase in cellulose (b) (4)
- The new tobacco product has a (b) (4) decrease in (b) (4)
- The ingredient (b) (4) is added to the new tobacco product
- The new tobacco product has a (b) (4) increase in (b) (4)
- The new tobacco product has a (b) (4) increase in (b) (4)
- The new tobacco product has a 3% increase in rolling paper mass
- The new tobacco product has a 4% increase in base paper basis weight
- The new tobacco product has a 1150% increase in base paper porosity

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. To support the change in ingredients, the applicant provided carbon monoxide, tar, and HPHC yields for RYO cigarettes constructed using the new and predicate tobacco products and the same commercial tobacco filler. The carbon monoxide, tar, and HPHC yields were decreased or only slightly increased in the new tobacco products. The decreases in carbon monoxide, tar, and HPHC yields also support the increase in base paper porosity (all products), decrease in paper mass (SE0013974 and SE0013975), and decrease in paper length and width (SE0013974 and SE0013975). Both the differences in base paper basis weight (all products) and paper mass (SE0013976) were minor, and these differences do not cause the new tobacco products to raise different questions of public health. The social science review and the finalized memorandum² conclude that based on OS's experience and the currently available evidence, the difference in product quantity, as well as differences in product length and width, do not cause the new tobacco product to raise different questions of public health. I concur with this conclusion. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products 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 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 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.

² See memorandum on product quantity changes, dated December 7, 2017.

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 SE0013974 - SE0013976, as identified on the cover page of this review.