Technical Project Lead (TPL) Memorandum: SE Report SE0003299

New Tobacco Product	
Product Name	OCB Organic Hemp 1 ¼ Size
Package Size	50 papers
Package Type	Booklet
Product ID	UPC 0-86400-00022-2
Applicant	Republic Tobacco, L.P.
Status	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Substantial Equivalence (SE) order	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2013.10.02 13:21:09 -04'00'

Matthew R. Holman, Ph.D.
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 David Ashley -S
Date: 2013.10.02 13:49:32 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

Table 1. Predicate Tobacco Product

Manufacturer	Republic Tobacco, L.P.
Product Name	JOB Tribal King Size
Package Size	32 papers
Package Type	Booklet
Product ID	UPC 0-86400-0036-9
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Claimed Status	Grandfathered Product

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original SE Report SE0003299 in June 2011. FDA sent the applicant an administrative advice and information request letter (A/I letter) for this SE Report. In response, the applicant submitted amendment SE0004178 to the original SE Report in March 2012. Following our review of the SE Report, we sent a scientific A/I letter to the applicant in August 2012. The applicant responded to the scientific A/I letter by amending their SE Report (SE0005141) in November 2012. FDA then sent a Preliminary Finding letter to the applicant in April 2013. The applicant responded to the Preliminary Finding letter by amending their SE Report (SE0008617) in May 2013.

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for SE0003299.

1.4. KEY DIFFERENCES BETWEEN NEW AND PREDICATE TOBACO PRODUCTS

The new tobacco product has the following key differences compared to the predicate tobacco product:

- Increase in package size (from 32 to 50 rolling papers)
- (b) (4)
- (b) (4)
- Decrease in paper length

2. ADMINISTRATIVE REVIEW

An administrative completeness review was completed by Stephanie Redus on May 23, 2012.

The administrative completeness review concluded that the SE Report was not administratively complete for the following reasons:

1. Health information summary required under section 910(a)(4) of the FD&C Act not provided
2. “Other features” described as a characteristic in section 910(a)(3)(B) of the FD&C Act not provided

The SE Report is now administratively complete because these two issues have been adequately addressed. In September 2012, FDA sent the applicant an A/I letter requesting a health information summary or a statement that the health information summary will be made available upon request. In October 2012, the applicant responded by stating that a health information summary will be made available upon request (SE0005021). The product characteristics needed to make a determination of substantial equivalence have been provided by the applicant, so there are no “other features” required at this time.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated May 23, 2012, concludes that the predicate tobacco product is an eligible predicate tobacco product, as the applicant established that the predicate tobacco product is grandfathered.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the new tobacco product is 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 review dated September 11, 2013, concludes that the new tobacco product is 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 Ciby Abraham, Ph.D. on August 9, 2012, and Michael Koenig, Ph.D. on April 10, 2013.

The final chemistry review concludes that the new tobacco product does not raise different questions of public health with regard to product composition. Both the new and predicate tobacco products are made of hemp, non-wood resources; there was no change in characteristics related to the use of hemp in the new and predicate products. The composition of the new tobacco product is nearly identical to the composition of the predicate product with the exception of a [redacted] used in the paper from (b) (4) [redacted] The primary impact of this (b) (4) [redacted] is a (b) (4) [redacted]. The engineering review (see below) examined the (b) (4) [redacted] and concluded that the difference between this in the new and predicate product did not cause the new tobacco product to raise different questions of public health. Overall, the chemistry review concludes that the differences in the identity or quantities of ingredients and additives between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Sabina Reilly on August 14, 2012, Christopher Brown on April 9, 2013, and Christopher Brown on July 23, 2013.

The final engineering review concludes that the new tobacco product does not raise different questions of public health with regard to product design. The design of the new and predicate tobacco products differ in the following ways:

- (b) (4) [redacted]
- Decrease in paper length (from 109 to 77 mm)
- [redacted] (b) (4)

The (b) (4) [redacted] is expected to lead to a (b) (4) [redacted], as observed. The applicant submitted studies examining the impact of [redacted]. Based on those studies, it is not expected that the [redacted] would affect tar or HPHC yields. Overall, the engineering review concludes that the differences in product design between the predicate and new tobacco products are such that the new tobacco product does not raise different questions of public health. To the extent that paper size is relevant to total tobacco product consumption, the decrease in paper length does not cause the new tobacco product to raise different questions of public health because consumers would be exposed to less smoke per cigarette. It is unclear how overall exposure to toxicants would be affected, as the limiting factor in consumption is more likely to be the quantity of tobacco available and use patterns than the size of each individual cigarette.

4.3. TOXICOLOGY

A toxicology review was completed by Michael Orr, Ph.D. on July 26, 2012.

The toxicology review raises the concern that the (b) (4) may lead to increased toxicant exposure, but defers to the chemistry and engineering reviewers to address this concern. As stated in the previous section of this memo, the applicant satisfied this concern by submitting studies regarding the (b) (4). Therefore, there are no differences in product toxicity between the predicate and new tobacco products, and the new tobacco product does not raise different questions of public health with regard to toxicity.

4.4. SOCIAL SCIENCE

Two social science reviews were completed by David Portnoy, Ph.D. on September 26, 2013, and September 27, 2013.

The September 27, 2013, social science review raises the concern about the term “organic hemp” in the name of the new tobacco product. The new tobacco product name includes the term “organic hemp,” while the predicate tobacco product name does not. It is possible that consumers may interpret the use of the term “organic” in this context to mean that the new tobacco product presents a reduced harm compared to tobacco products that do not include the term “organic” on their label. The review indicates that there is no direct evidence that characterizes how consumers perceived “organic” specifically as it applies to cigarette rolling papers. In the context of an evaluation of the descriptor “organic” for rolling papers, the review concludes that available evidence is not sufficient to establish that the term would be perceived by consumers as reducing risk or exposure to harmful substances when compared to other products. Therefore, the new tobacco product does not raise different questions of public health with regard to product appeal.

The applicant did not provide a health information summary. To fulfill the provisions of section 910(a)(4) of the FD&C Act, the applicant stated that it will make such information available upon request by any person. The September 26, 2013, review concludes that this is acceptable.

5. ENVIRONMENTAL DECISION

On October 2, 2013, Hoshing Chang, Ph.D. prepared a finding of no significant impact (FONSI) that was supported by an Environmental Assessment. The FONSI was signed by RADM David L. Ashley on October 2, 2013.

6. CONCLUSION AND RECOMMENDATION

The key differences in characteristics between the new and predicate tobacco products consist primarily of the following:

- Increase in package size (from 32 to 50 rolling papers)
- (b) (4)
- (b) (4)
- Decrease in paper length

To the extent that paper size is relevant to total tobacco product consumption, the decrease in paper length does not cause the new tobacco product to raise different questions of public health because consumers would be exposed to less smoke per cigarette. It is unclear how overall exposure to toxicants would be affected, as the limiting factor in consumption is more likely to be the quantity of tobacco available and use patterns than the size of each individual cigarette.

The and (b) (4) are expected to lead to a , as observed. The applicant submitted studies examining the impact of . Based on those studies, it is not expected that the would affect tar or HPHC yields. Therefore, the and (b) (4) does not cause the new tobacco product to raise different questions of public health.

Generally, increases in tobacco product package size could lead to users consuming more tobacco product. However, the difference in package size in this SE Report does not seem likely to change use patterns. The number of roll-your-own cigarettes smoked each day is more likely to be related to the amount of roll-your-own tobacco available to the user and less likely to be related to the number of roll-your-own papers available.

The new tobacco product name includes the term “organic hemp,” while the predicate tobacco product name does not. It is possible that consumers may interpret the use of the term “organic” in this context to mean that the new tobacco product presents a reduced harm compared to tobacco products that do not include the term “organic” on their label. There is no direct evidence that characterizes how consumers perceived “organic” specifically as it applies to cigarette rolling papers. In the context of an evaluation of the descriptor “organic” for rolling papers, the available evidence is not sufficient to establish that the term would be perceived by consumers as reducing risk or exposure to harmful substances when compared to other products.

The applicant did not provide a health information summary. To fulfill the provisions of section 910(a)(4) of the FD&C Act, the applicant stated that it will make such information available upon request by any person.

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

The new tobacco product is 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 product does not raise different questions of public health. I concur with these reviews and recommend that an SE order be issued.

In addition, an order letter can be issued because FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order should be issued for the new tobacco product in SE0003299, as identified on the cover page of this memo.