Technical Project Lead (TPL) Review: SE0009681

SE0009681: SFNTC Branded Rolling Papers 50 ct	
Package Type	Booklet
Package Quantity	50 papers
Length	76.5 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Manufactured by (b) (4) [redacted].
Applicant	Santa Fe Natural Tobacco Company, Inc.
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2018.12.13 14:45:12 -05'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
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)

Matthew R. Holman -S 2018.12.13 15:11:08 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0009681: SFNTC Branded Rolling Papers 50 ct	
Product Name	Roor King Size Slim
Package Type	Booklet
Package Quantity	33 papers
Length	108 mm
Width	44 mm
Characterizing Flavor	None

The predicate tobacco product is a roll-your-own (RYO) rolling paper manufactured by (b) (4) [redacted].

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the SE Report on August 30, 2013. In the SE Report, the applicant identified the new product as a rolling paper tobacco product and compared the new rolling paper tobacco product with a predicate rolling paper tobacco product. FDA issued an Acknowledgement letter on December 30, 2013. In the Acknowledgement letter, FDA referred to the new product as RYO paper. On January 3, 2014, FDA issued a Notification letter informing the applicant that scientific review would commence on February 17, 2014; the reviews subsequently compared the new rolling paper to the predicate rolling paper. FDA issued a Preliminary Finding letter on March 21, 2014 to request evidence to demonstrate commercial marketing as of February 15, 2007 of the predicate tobacco product. In response, FDA received an amendment (SE0010370) on April 9, 2014. FDA issued an Advice/Information (A/I) Request letter requesting additional scientific information on June 25, 2015. In response, FDA received an amendment (SE0012303) on August 24, 2015. FDA issued a Preliminary Finding letter with additional scientific deficiencies on December 17, 2015. In response, FDA received an amendment (SE0012795) on January 15, 2016. FDA held a teleconference with the applicant on February 19, 2016, to request clarifying information regarding the method used to generate carbon monoxide data. In response to the teleconference, FDA received an amendment (SE0012980) on February 25, 2016. FDA issued a Preliminary Finding letter on January 5, 2017 requesting environmental information. In response, FDA received an amendment (SE0013891) on February 3, 2017. On February 28, 2017, FDA sent an email to the applicant requesting clarifying information related to environmental considerations for their SE Report. In response, the applicant submitted an amendment (SE0013968).

In response to the January 5, 2017 Preliminary Finding letter, the applicant provided information about the packaging of the new product in amendment SE0013981. In the amendment, the applicant included images of the new product identified in SE0009681. The images clearly showed that the new product will be co-packaged with RYO tobacco filler. FDA held teleconferences with the applicant on October 17, 2017 and November 7, 2017, requesting product identifying information for the tobacco filler and the names of the co-packages. In response, FDA received amendments containing the requested information on October 19, 2017 (SE0014383) and on November 17, 2017 (SE0014405),

respectively.[1] These amendments show that the new product, RYO paper, subject to this review will be co-packaged with grandfathered tobacco filler.[2]

Product Name	SE Report	Amendments
SFNTC Branded Rolling Papers 50 ct	SE0009681	SE0010370 SE0012303 SE0012795 SE0012980 SE0013891 SE0013968 SE0014383 SE0014405 SE0014729

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Ouida Holmes on December 30, 2013.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco product, referenced as Roor King Size Slim, is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated April 2, 2014 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.[3]

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[1] According to the applicant's amendment, the applicant is intending to co-package the new tobacco product that is the subject of this SE Report (rolling papers) with RYO filler in two different ways, one of which does not result in a new tobacco product and one of which does result in a new tobacco product. However, the new tobacco product that is the subject of this SE Report is just the rolling paper product and this review only evaluates that new tobacco product. For the co-packaging of the rolling paper product with the RYO filler that results in a new tobacco product, the applicant would need to seek premarket authorization (unless that co-packaged product is grandfathered).

[2] Separate from the SE Review, on May 15, 2018, the Office of Compliance held a teleconference to request the applicant to provide certain information about the label of the new product and co-packages. The applicant's response containing the requested information was received on May 18, 2018 (SE0014729).

[3] Because of a misunderstanding, a second GF review was conducted on December 5, 2017. A GF review was conducted on February 2, 2018 for the RYO filler. This GF review of the RYO filler was conducted in error, as both the new and predicate tobacco products are rolling papers.

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), (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE reviews dated April 27, 2016, August 10, 2016, May 5, 2017, January 12, 2018, May 18, 2018, and June 4, 2018 conclude 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 for the new tobacco product:

4.1. CHEMISTRY

Chemistry reviews were completed by Christina Young on July 14, 2014, and October 14, 2015, and by Melissa McCulloch on February 26, 2016.

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

- Addition of (b) (4)
- 5% decrease in (b) (4)
- Decrease in paper dimensions

The applicant has demonstrated that the addition of (b) (4), decrease in (b) (4) and decrease in paper dimensions does not cause the new product to raise different questions of public health as the applicant provided TNCO yields which showed a reduction in TNCO yields (24-46%) in the new tobacco product compared to the predicate product. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Tiffany Petty on July 21, 2014, and October 23, 2015.

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

- 29% decrease in paper length (from 108 to 76.5 mm)
- 28% decrease in paper mass (from 72 to 52 mg/paper)

These differences in characteristics are likely to decrease the amount of tobacco and paper combusted and consumed by users on a per unit of use basis, which would result in a decrease

in TNCO yields, as demonstrated by the applicant in the provided TNCO smoke yields. Therefore, the differences in characteristics do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews[4] were completed by Susan Chemerynski on May 28, 2015, and March 22, 2016.

The final toxicology review concludes that the new tobacco product has different characteristics related to toxicology compared to the predicate tobacco product, but the difference does not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Addition of (b) (4)

The applicant has demonstrated that the addition of (b) (4) does not cause the new product to raise different questions of public health as the applicant provided TNCO yields which showed a reduction in TNCO yields (24-46%) in the new tobacco product compared to the predicate product. Therefore, the difference in characteristics between the new and predicate tobacco product does not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

4.4. SOCIAL SCIENCE

Social science reviews were completed by Amber Koblitz on July 14, 2014, and by Wendy Slavit on October 16, 2015.

The final social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following differences:

- 29% decrease in paper length (from 108 to 76.5 mm)
- 52% increase in package quantity (from 33 to 50 papers per booklet)

The review concludes that there is currently no scientific evidence available which demonstrates that these increases in paper quantity could cause the new product to raise different questions of public health. Therefore, the differences in characteristics between the new and corresponding predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[5] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time,

[4] A memorandum by Matthew Holman on November 2, 2015, explains that a toxicology review of the amendment responding to the A/I letter was not completed because the applicant did not submit HPHC data at that time for toxicology review.
[5] *See* memorandum on product quantity changes, dated December 7, 2017.

changes in tobacco product quantity does not cause new tobacco product to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco product to raise different questions of public health from a social science perspective.

Although not addressed in the final social science review, there was also a 29% decrease in paper length between the new tobacco product and the predicate tobacco product. There is no available scientific evidence on the influence of differences in paper length on consumer perceptions of harm or use intentions to indicate that this minor difference could cause the new tobacco product to raise different questions of public health from a social science perspective. Therefore, the difference in paper length does not cause the new product to raise difference questions of public health.

The review also evaluated the health information summary. The applicant originally submitted a health information summary, which was reviewed by social science. The first social science review noted that the health information summary potentially could cause a violation of section 911 of the FD&C Act. In response to the A/I letter, the applicant indicated that it would instead provide any health information related to the new tobacco product upon request by any party.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 13, 2017, by Hans Rosenfeldt on May 15, 2018, and Kimberly Benson, Ph.D. on December 13, 2018. The FONSI was supported by an environmental assessment prepared by FDA on April 13, 2017, May 1, 2018, and December 13, 2018.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate product:

- Addition of (b) (4)
- 5% decrease in (b) (4)
- 29% decrease in paper length
- 28% decrease in paper mass
- 52% increase in package quantity (from 33 to 50 papers per booklet)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health compared to the predicate product. The applicant measured TNCO yields by filling the new rolling paper and the predicate rolling paper with the same tobacco at the same packing density to evaluate the influence of the addition of (b) (4), decrease in (b) (4), and decrease in paper dimensions and mass. The TNCO yields decreased in the new tobacco product compared to the predicate product by 24-46% demonstrating that these differences in characteristics do not cause the new product to raise different questions of public health. The social science review and memorandum[6] on product quantity changes conclude that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions

[6] *See* memorandum on product quantity changes, dated December 7, 2017.

of public health; additionally, as explained above, there is no available scientific evidence on the influence of differences in paper length on consumer perceptions of harm or use intentions to indicate that this minor difference could cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new tobacco product and the predicate product do not cause the new product 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., were commercially marketed in the United States other than exclusively in test markets 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 product are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0009681, as identified on the cover page of this review.