FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014118

SE0014118: Bugler Leaf .65 oz Pouch	
Package Type	Pouch
Package Quantity	18.43 g
Characterizing Flavor	None
Attributes	
Applicant	Scandinavian Tobacco Group Lane Ltd.
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Tobacco Filler
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.04.19 13:02:36 -04'00'

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: 2018.04.19 13:22:15 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND 4

1.1. PREDICATE TOBACCO PRODUCT 4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW 4
1.3. SCOPE OF REVIEW 5

2. REGULATORY REVIEW 5

3. COMPLIANCE REVIEW 5

4. SCIENTIFIC REVIEW 6

4.1. ENGINEERING 6
4.2. SOCIAL SCIENCE 7

5. ENVIRONMENTAL DECISION 7

6. CONCLUSION AND RECOMMENDATION 8

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0014118: Bugler Leaf .65 oz Pouch	
Product Name[1]	Bulk Golden Virginia Cigarette Cut
Package Type	Bag
Package Quantity	2267.96 g
Characterizing Flavor	None

The predicate tobacco product is Roll-Your-Own tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 25, 2017, FDA received an SE Report from Scandinavian Tobacco Group Lane Ltd (STG Lane) designated as a Product Quantity Change SE Report by the applicant. FDA issued an Acknowledgment letter on June 1, 2017. On June 27, 2017, FDA received an unsolicited amendment from STG Lane containing updated information on the predicate tobacco product name (SE0014187). On August 18, 2017, FDA held a teleconference to request that the applicant clarify the predicate tobacco product name. On August 18, 2017, FDA received the applicant's response (SE0014249). FDA issued a Preliminary Finding (PFind) letter on August 23, 2017. On September 25, 2017, FDA received the applicant's partial response to the PFind letter (deficiencies 3-11 only; amendment SE0014345). On September 25, 2017, FDA also received an extension request for additional time to address deficiencies 1 and 2 of the PFind letter, which were social science deficiencies related to changes in package quantity and package format (SE0014346). In the original application, the applicant designated the report as a Product Quantity Change SE Report, and included a certification statement to reflect that the only difference between the new and predicate tobacco products is the product quantity change. Upon further review of the amendments, FDA noted that the applicant's certification statement did not account for differences in the container closure systems between the new and predicate tobacco products. The predicate tobacco product is packaged in a polyethylene bag and the new tobacco product is packaged in a laminated foil rollstock pouch. Since the differences between the new and predicate tobacco products are not limited to a difference in product quantity, FDA reclassified SE0014118 from a Product Quantity Change SE Report to a full SE Report on December 21, 2017.[2] In addition, the final social science review dated December 7, 2017, stated that there were no remaining deficiencies from the social science's perspective because, based on the currently available evidence, the changes in product quantity do not cause the new tobacco product to raise different questions of public health. Additionally, although the packaging here is a component or part of the tobacco product, review of the impact of the difference in packaging on consumer perception and use was not warranted. This is because the reviews did not identify any differences that were intended or reasonably expected to alter or affect the new tobacco product's performance, composition,

[1] On April 5, 2017, the predicate tobacco product underwent a name change from "BULK GOLDEN VIRGINIA CIGARETTE CUT" to "BUGLER LEAF"

[2] See December 21, 2017, memorandum "Reclassification of SE0014118 from Product Quantity Change SE Report to Full SE Report and associated deficiencies"

constituents, or characteristics in a manner that could impact the appeal of the product. Therefore, deficiencies 1 and 2 noted in the August 23, 2017, PFind letter no longer remain, and the September 25, 2017, extension request is moot. On December 21, 2017, FDA issued a PFind correction letter rescinding deficiencies 1 and 2 and adding three new deficiencies regarding the certification statement and design parameters. On January 19, 2018, FDA received the applicant's response to the PFind correction letter (SE0014482). On March 5, 2018, FDA received an unsolicited amendment including a table that was inadvertently omitted from the January 19, 2018, amendment responding to the PFind correction letter (SE0014566). Based on a preliminary assessment by the Technical Project Lead for this SE Report, it was determined that the information in the untimely submitted amendment did not impact the conclusions of the ongoing scientific reviews or of this TPL review. Accordingly, the late-submitted amendment was substantively reviewed.

Product Name	SE Report	Amendments
Bugler Leaf .65 oz Pouch	SE0014118	SE0014187 SE0014249 SE0014345 SE0014346 SE0014482 SE0014566

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Lauren DeBerry on June 1, 2017, and August 23, 2017.

The final review concludes that the SE Report is 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 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 August 23, 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.[3]

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

[3] An addendum review was completed on April 18, 2018, to clarify that the characterizing flavor for the predicate tobacco product is "none." The addendum review does not change the conclusion of the initial grandfather determination dated August 23, 2017.

FD&C Act. The OCE reviews dated November 30, 2017, and April 19, 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:

4.1. ENGINEERING

An engineering review was completed by James Cheng on March 12, 2018.[4]

The engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- A decrease in tobacco filler mass from 2267.96 g to 18.43 g (99.2% decrease)
- A change in packaging from polyethylene bag to laminated foil rollstock pouch

The applicant submitted an updated certification statement which stated that the only differences between the new and predicate tobacco products are product quantity and packaging material and affirmed that there are no other differences between the new and predicate tobacco products. The applicant submitted target specifications and range limits for design parameters for the new and predicate tobacco products, and test data for the predicate tobacco product (with the exception of tobacco cut width). All of the provided specifications and range limits, except for the tobacco filler mass, are identical for the new and predicate tobacco products, and the test data provided for the predicate tobacco product are within the stated upper and lower range limits for tobacco filler mass and tobacco moisture. There are no differences in tobacco filler specifications (with the exception of tobacco filler mass) or production processes between the new and predicate tobacco products.

Furthermore, the applicant's certification statement demonstrated that the new and predicate tobacco products are both RYO filler tobacco products (i.e., non-moist tobacco) that are identical other than the change in product quantity and packaging materials. Accordingly, even though the applicant did not provide test data for the new tobacco product demonstrating that its specifications are met, such data were not necessary given that the new and predicate tobacco products are both non-moist RYO products that are identical other than the differences in product quantity and packaging materials. Given the likelihood that the particular difference in packaging materials would not impact the stability of the non-moist RYO tobacco filler, the difference in packaging materials does not cause the new tobacco product to raise different questions of public health. Additionally, given the likelihood that any testing performed on the new tobacco product (which is only a repackaging of the identical tobacco filler of the predicate tobacco product in a different quantity) would not show any differences because the product component being tested (non-moist tobacco filler) is identical to the predicate tobacco product, the differences between the new and predicate tobacco products do not cause the new tobacco

[4] An addendum to the engineering review was completed on April 19, 2018.

product 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 product to raise different questions of public health from an engineering perspective.

4.2. SOCIAL SCIENCE

Social science reviews were completed by Rhonda Moore on August 22, 2017, and Joelle Robinson on December 7, 2017.

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:

- A decrease in product quantity from 2267.96 g to 18.43 g (99.2% decrease)
- A change in package format from bag to pouch

The first social science review states that it is possible that a product quantity change of this magnitude (99.2%) might affect consumer perceptions and use of the product. However, the Office of Science (OS) developed a memorandum[5] summarizing its current thinking on product quantity changes. The memorandum states that based on the currently available scientific evidence regarding consumer perception and use, OS has concluded that, at this time, changes in product quantity do not cause new tobacco products to raise different questions of public health. The final social science review cites this memorandum to support its conclusion that the difference in product quantity does not cause the 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, and no deficiencies remain.

The first social science review also states that the change in package format from bag to pouch may make the new tobacco product more appealing to new consumers than the predicate tobacco product. However, the final social science review states that the packaging here is a component or part of the tobacco product, and in certain circumstances, review of the impact of a difference in packaging on consumer perception and use is warranted. Here, however, the social science reviewer's analysis was based on a change in package type 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. Therefore, no deficiencies remain.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Mehran Niazi on August 22, 2017.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 18, 2018. The FONSI was supported by an environmental assessment prepared by FDA on April 18, 2018.

[5] See memorandum dated December 7, 2017

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a decrease in product quantity from 2267.96 g to 18.43 g and change in packaging from polyethylene bag to laminated foil rollstock pouch.[6]

The final social science review concludes that the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Based on currently available scientific evidence regarding consumer perception and use, changes in product quantity do not cause new tobacco products to raise different questions of public health. The difference in package format does not change the product's performance, composition, constituents, or characteristics in a manner that could impact the appeal of the product. I concur with the conclusion of the social science review. The final engineering review concludes that because the new and predicate tobacco products are both non-moist RYO products that are identical other than differences in packaging material and product quantity, those differences do not cause the new tobacco product to raise different questions of public health from an engineering perspective. I concur with the conclusion of the engineering review.

Furthermore, although the chemistry review discipline did not review the change in packaging materials, the differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Given the likelihood that this specific change in packaging materials for this type of product (i.e., non-moist RYO tobacco filler) does not impact tobacco moisture, the change in packaging materials does not cause the new tobacco product to raise different questions of public health. In addition, given the likelihood that differences in the polyethylene comprising the packaging materials would not impact composition of and/or leach into the tobacco filler, these differences do not cause the new tobacco 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., was 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 reviews conclude that the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to 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 SE0014118, as identified on the cover page of this review.

[6] As noted in amendment SE0014345, the predicate tobacco product container closure system is a low density polyethylene bag and the new tobacco product container closure system is a high density polyethylene pouch.