FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0011198

| SE0011198: Bugler Cigarette Rolling Papers | |
|---|---|
| Package Type | Booklet |
| Package Quantity | 50 papers |
| Length | 70 mm |
| Width | 40 mm |
| Characterizing Flavor[1] | None |
| **Attributes** | |
| Applicant | Scandinavian Tobacco Group Lane Ltd. |
| Report Type | Regular Product Quantity Change |
| Product Category | Roll-Your-Own Tobacco |
| Product Sub-Category | Rolling Papers |
| **Recommendation** | |
| Issue a Substantially Equivalent (SE) order. | |

[1] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

**Technical Project Lead (TPL):**

Digitally signed by Colleen K. Rogers -S
Date: 2018.01.31 09:48:01 -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: 2018.01.31 14:07:24 -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:

| SE0011198: Bugler Cigarette Rolling Papers | |
|---|---|
| **Product Name** | Bugler Gummed Cigarette Papers |
| **Package Type** | Booklet |
| **Package Quantity** | 115 papers |
| **Length** | 70 mm |
| **Width** | 40 mm |
| **Characterizing Flavor**[2] | None |

The predicate tobacco product is roll-your-own rolling papers manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2015, Scandinavian Tobacco Group Lane Ltd. submitted a Product Quantity Change SE Report. FDA issued an Acknowledgment letter to the applicant on April 24, 2015. On May 14, 2015, FDA requested additional unique identification information. In response, the applicant submitted an amendment (SE0011894) on May 27, 2015. After an environmental review was conducted, FDA requested clarification on the Environmental Assessment (EA) on May 18, 2017. On May 25, 2016, the applicant submitted a request for additional time to respond to the EA Information Request (SE0013395). The applicant responded to the EA Information Request on June 6, 2016 (SE0013416).

| Product Name | SE Report | Amendments |
|---|---|---|
| Bugler Cigarette Rolling Papers | SE0011198 | SE0011894<br>SE0013395<br>SE0013416 |

## 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 Grace Kaiyuan on April 24, 2015, and Lauren DeBerry on November 3, 2017.

The final review concludes that the SE Report is administratively complete.

[2] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

## 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 June 12, 2015, 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 reviews 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 June 12, 2015; September 15, 2015; October 14, 2015; January 13, 2016; April 27, 2016; July 27, 2016; October 14, 2016; February 13, 2017; and January 26, 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 discipline:

### 4.1. SOCIAL SCIENCE

A social science review was completed by Joelle Robinson on August 4, 2015.

The 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 between the new and predicate tobacco products:

- A decrease in product quantity from 115 papers to 50 papers (56.5%)

The social science reviewer states that there is currently no available scientific evidence that changes in the quantity of rolling papers of this magnitude would cause the new tobacco product to raise different questions of public health from a social science perspective. The review concludes that the differences between the new and predicate tobacco products 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[3] 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 product to raise different questions of public health from a social science perspective.

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

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 31, 2018. The FONSI was supported by an environmental assessment prepared by FDA on January 31, 2018.

## 6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 115 to 50 cigarette rolling papers.

The social science review and the recently finalized memorandum[4] conclude that based on OS's experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

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 product is currently in compliance with the FD&C Act.

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 SE0011198, as identified on the cover page of this review.

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