FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0014067

| SE0014067: SAMSON HALFZWARE | |
|---|---|
| Package Type | Pouch |
| Package Quantity | 40 g |
| Characterizing Flavor[1] | 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. | |

[1] As provided by the applicant's certification statement, which stated that "the only change between the new and predicate product is the removal of a 60-leaf booklet of rolling papers from the predicate product." Because of the nature of the change certified by the applicant, FDA did 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: 2017.11.13 14:34:13 -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: 2017.11.13 19:50:03 -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 following predicate tobacco product:

| SE0014067: SAMSON HALFZWARE | |
|---|---|
| **Product Name** | SAMSON HALFZWARE |
| **Tobacco Filler Package Type** | Pouch |
| **Package Quantity** | 40 g |
| **Rolling Paper Package Type** | Booklet |
| **Package Quantity** | 60 rolling papers |
| **Length** | 69 mm |
| **Width** | 36 mm |
| **Characterizing Flavor** | None |

The predicate tobacco product is a Roll-Your-Own tobacco co-package, containing tobacco filler and rolling papers, and is manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 27, 2017, FDA received a self-titled Product Quantity Change SE Report from Scandinavian Tobacco Group Lane Ltd. As found in *Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, 202 F. Supp. 3d 31, 55-57 (D.D.C. 2016), a change in product quantity results in a new tobacco product subject to premarket review. The proposed modification resulting in the new tobacco product in this SE Report is the complete removal of a product subcategory, Roll-Your-Own (RYO) rolling papers, from the predicate tobacco product, which is a RYO co-package consisting of tobacco filler and a booklet of rolling papers. FDA determined that this proposed modification is not a change in product quantity because the proposed change is not a change in the number of rolling paper sheets, but instead the removal of all rolling paper sheets in their entirety. FDA has nonetheless accepted the applicant's certification that the removal of the rolling papers is the only change made to the new tobacco product as compared to the predicate tobacco product. Generally, the information submitted by the applicant regarding any differences in characteristics between the new and predicate tobacco products guides the assignment of scientific review disciplines. In the SE Report that is the subject of this review, the applicant noted that the new tobacco product differs from the predicate tobacco product only with respect to the removal of the booklet of rolling papers and provided a certification statement attesting that all other characteristics between the new and predicate tobacco products are identical. Based on this information, FDA determined that scientific review was needed only to evaluate whether the removal of the booklet of rolling papers causes the new tobacco product to raise different questions of public health.

FDA issued an Acknowledgment letter to the applicant on May 2, 2017. Also on the same day, FDA requested additional information regarding the predicate tobacco product through a telephone call to the applicant. The applicant responded on May 10, 2017 (SE0014080). After an environmental review was conducted on July 21, 2017, FDA issued a Preliminary Finding

letter on July 26, 2017. The Preliminary Finding letter identified environmental deficiencies in the applicant's SE Report. The applicant submitted a response (SE0014244) on August 17, 2017.

| Product Name | SE Report | Amendments |
|---|---|---|
| SAMSON HALFZWARE | SE0014067 | SE0014080<br>SE0014244 |

### 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 May 2, 2017, and July 25, 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 as of February 15, 2007). The OCE review dated June 8, 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 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 review dated October 13, 2017, concludes that the new tobacco product is in compliance with the FD&C Act.

## 4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for social science. Because the only difference between the new and predicate tobacco products is the removal of a booklet of rolling papers, reviews by other scientific disciplines are not warranted.

### 4.1. SOCIAL SCIENCE

A social science review was completed by Joelle Robinson on June 21, 2017.

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 difference between the new and predicate tobacco products:

- The predicate tobacco product is a co-package of RYO tobacco filler and a 60-leaf booklet of rolling papers, while the new tobacco product contains only RYO tobacco filler

The applicant states that this change is being made to comply with new European regulations. The social science reviewer states that it is unclear if and how the removal of co-packaged rolling papers in a pouch of roll-your-own tobacco would affect consumer perceptions and use intentions related to the product. Therefore, the reviewer concluded that, from a social science perspective, the specific difference between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health.

As explained below, I agree with the social science reviewer that for the type of product in this SE Report, RYO tobacco filler, the removal of a booklet of rolling papers would not cause the proposed new tobacco product to raise different questions of public health. While not explained in the social science review, I find that in the context that all other product characteristics between the new and predicate tobacco products in this SE Report are the same, the removal of the booklet of rolling papers is not expected to adversely affect consumer perception or use intentions. Based on FDA's experience and knowledge it is very unlikely that youth would initiate tobacco use with the new tobacco product that is the subject of this SE Report. This is because RYO tobacco filler requires other tobacco products like cigarette rolling papers and filters in order to be assembled into a finished product that is ready for use; therefore, the likelihood of youth initiating with a filler-only tobacco product is low. I also note that the removal of the booklet of rolling papers from the co-package would likely make the new tobacco product less convenient to use because rolling papers would have to be purchased separately. Based on the foregoing, as well as FDA's general experience reviewing SE Reports for this type of product, I find that, based on the current state of the evidence, the removal of a booklet of rolling papers from the RYO tobacco co-package does not cause the new tobacco product to raise different questions of public health.

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 27, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 27, 2017.

## 6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for the removal of a booklet of rolling papers.

The social science review concludes that this specific difference does not cause the new tobacco product to raise different questions of public health. I concur with the conclusion of the social science review.

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.

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 products in SE0014067, as identified on the cover page of this review.