



**Technical Project Lead (TPL) Review:**

**SE0000169, SE0000171, SE0000187, SE0000188,  
SE0000197, SE0000207, SE0000230, SE0000231,  
SE0000244, SE0000252**

| <b>SE0000169: Real Menthol 3 oz Medium Bag</b> |  |
|--|--|
| Package Type                                   | Bag  |
| Package Quantity                               | 85 g   |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | Menthol  |
| <b>SE0000171: Real Silver 8 oz Large Bag</b>   |  |
| Package Type                                   | Bag  |
| Package Quantity                               | 226.8 g  |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | None   |
| <b>SE0000187: Top Turkish 0.6 oz Pouch</b>     |  |
| Package Type                                   | Roll-Your-Own Co-Package (Tobacco Filler and Rolling Papers) |
| Tobacco Filler Name                            | Top Turkish 0.6 oz Pouch                                     |
| Package Type                                   | Pouch  |
| Package Quantity                               | 0.6 oz   |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | None   |
| Rolling Paper Name                             | Top gummed flat booklet                                      |
| Package Type                                   | Booklet  |
| Package Quantity                               | 32 (papers)  |
| Length   | 70 mm  |
| Width  | 39 mm  |
| Characterizing Flavor                          | None   |

| <b>SE0000188: Top Turkish 6 oz Canister</b>        |  |
|--|--|
| Package Type                                       | Roll-Your-Own Co-Package (Tobacco Filler and Rolling Papers) |
| Tobacco Filler Name                                | Top Turkish 6 oz Canister                                    |
| Package Type                                       | Canister   |
| Package Quantity                                   | 170.1 g  |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | None   |
| Rolling Paper Name                                 | Top gummed flat booklet                                      |
| Package Type                                       | Booklet  |
| Package Quantity                                   | 2 booklets of 100 (papers)                                   |
| Length   | 70 mm  |
| Width  | 39 mm  |
| Characterizing Flavor                              | None   |
| <b>SE0000197: Real Menthol 8 oz Large Bag</b>      |  |
| Package Type                                       | Bag  |
| Package Quantity                                   | 226.8 g  |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | Menthol  |
| <b>SE0000207: Real Full Flavor 8 oz Large Bag</b>  |  |
| Package Type                                       | Bag  |
| Package Quantity                                   | 226.8 g  |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | None   |
| <b>SE0000230: Real Gold 3 oz Medium Bag</b>        |  |
| Package Type                                       | Bag  |
| Package Quantity                                   | 85 g   |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | None   |
| <b>SE0000231: Real Full Flavor 3 oz Medium Bag</b> |  |
| Package Type                                       | Bag  |
| Package Quantity                                   | 85 g   |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | None   |
| <b>SE0000244: Real Gold 8 oz Large Bag</b>         |  |
| Package Type                                       | Bag  |
| Package Quantity                                   | 226.8 g  |
| Tobacco Cut Size                                   | (b) (4)  |
| Characterizing Flavor                              | None   |

| SE0000252: Real Silver 3 oz Medium Bag      |   |
|---|---|
| Package Type                                | Bag   |
| Package Quantity                            | 85 g  |
| Tobacco Cut Size                            | (b) (4)   |
| Characterizing Flavor                       | None  |
| Common Attributes of SE Reports             |   |
| Applicant                                   | Top Tobacco, L.P.   |
| Report Type                                 | Regular   |
| Product Category                            | Roll-Your-Own   |
| Product Sub-Category                        | Roll-Your-Own Tobacco Filler: SE0000169, SE0000171, SE0000197, SE0000207, SE0000230, SE0000231, SE0000244, and SE0000252<br>Roll-Your-Own Co-Package: SE0000187 and SE0000188 |
| Recommendation                              |   |
| Issue Substantially Equivalent (SE) orders. |   |

**Technical Project Lead (TPL):**

|                                |  |
|--------------------------------|--|
| <p><b>Todd L. Cecil -S</b></p> | <p>Digitally signed by Todd L. Cecil -<br/>S<br/>Date: 2017.09.05 14:51:43 -04'00'</p> |
|--------------------------------|--|

Todd L. Cecil, 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)

|   |
|---|
| <p>Digitally signed by Matthew R. Holman -S<br/>Date: 2017.09.05 16:23:13 -04'00'</p> |
|---|

Matthew R. Holman, Ph.D.  
Director  
Division of Product Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

| <b>SE0000169: Real Menthol 3 oz Medium Bag</b> |  |
|--|--|
| Product Name                                   | TOP MENTHOL CANISTER   |
| Package Type                                   | Can  |
| Package Quantity                               | 170.1 g  |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | Menthol  |
| Rolling Paper Name                             | Top gummed flat booklet                                      |
| Package Type                                   | Booklet  |
| Package Quantity                               | 2 booklets of 100 (papers)                                   |
| Length   | 70 mm  |
| Width  | 39 mm  |
| Characterizing Flavor                          | Menthol  |
| <b>SE0000171: Real Silver 8 oz Large Bag</b>   |  |
| Product Name                                   | GAM/ULTLTE, 36 BAGS/CASE                                     |
| Package Type                                   | Bag  |
| Package Quantity                               | 170.1 g  |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | None   |
| <b>SE0000187: Top Turkish 0.6 oz Pouch</b>     |  |
| Product Name                                   | TOP REG. POUCH   |
| Package Type                                   | Roll-Your-Own Co-Package (Tobacco Filler and Rolling Papers) |
| Tobacco Filler Name                            | Top Regular 0.6 oz Pouch                                     |
| Package Type                                   | Pouch  |
| Package Quantity                               | 17 g   |
| Tobacco Cut Size                               | (b) (4)  |
| Characterizing Flavor                          | None   |
| Rolling Paper Name                             | Top gummed flat booklet                                      |
| Package Type                                   | Booklet  |
| Package Quantity                               | 32 (papers)  |
| Length   | 70 mm  |
| Width  | 39 mm  |
| Characterizing Flavor                          | None   |
| <b>SE0000188: Top Turkish 6 oz Canister</b>    |  |
| Product Name                                   | TOP REG. CAN   |
| Package Type                                   | Roll-Your-Own Co-Package (Tobacco Filler and Rolling Papers) |

|   |                            |
|---|----------------------------|
| Tobacco Filler Name                               | Top Regular 6 oz Pouch     |
| Package Type                                      | Pouch                      |
| Package Quantity                                  | 170.1 g                    |
| Tobacco Cut Size                                  | (b) (4)                    |
| Characterizing Flavor                             | None                       |
| Rolling Paper Name                                | Top gummed flat booklet    |
| Package Type                                      | Booklet                    |
| Package Quantity                                  | 2 booklets of 100 (papers) |
| Length  | 70 mm                      |
| Width   | 39 mm                      |
| Characterizing Flavor                             | None                       |
| <b>SE0000197: Real Menthol 8 oz Large Bag</b>     |                            |
| Product Name                                      | TOP MENTHOL CANISTER       |
| Package Type                                      | Can                        |
| Package Quantity                                  | 170.1 g                    |
| Tobacco Cut Size                                  | (b) (4)                    |
| Characterizing Flavor                             | Menthol                    |
| Rolling Paper Name                                | Top gummed flat booklet    |
| Package Type                                      | Booklet                    |
| Package Quantity                                  | 2 booklets of 100 (papers) |
| Length  | 70 mm                      |
| Width   | 39 mm                      |
| Characterizing Flavor                             | Menthol                    |
| <b>SE0000207: Real Full Flavor 8 oz Large Bag</b> |                            |
| Product Name                                      | TOP REG. CAN               |
| Package Type                                      | Can                        |
| Package Quantity                                  | 170.1 g                    |
| Tobacco Cut Size                                  | (b) (4)                    |
| Characterizing Flavor                             | None                       |
| Rolling Paper Name                                | Top gummed flat booklet    |
| Package Type                                      | Booklet                    |
| Package Quantity                                  | 2 booklets of (100 papers) |
| Length  | 70 mm                      |
| Width   | 39 mm                      |
| Characterizing Flavor                             | None                       |
| <b>SE0000230: Real Gold 3 oz Medium Bag</b>       |                            |
| Product Name                                      | TOP LITE CAN               |
| Package Type                                      | Can                        |
| Package Quantity                                  | 170.1 g                    |

|  |                            |
|--|----------------------------|
| Tobacco Cut Size                                   | (b) (4)                    |
| Characterizing Flavor                              | None                       |
| Rolling Paper Name                                 | Top gummed flat booklet    |
| Package Type                                       | Booklet                    |
| Package Quantity                                   | 2 booklets of 100 (papers) |
| Length   | 70 mm                      |
| Width  | 39 mm                      |
| Characterizing Flavor                              | None                       |
| <b>SE0000231: Real Full Flavor 3 oz Medium Bag</b> |                            |
| Product Name                                       | TOP REG. CAN               |
| Package Type                                       | Can                        |
| Package Quantity                                   | 170.1 g                    |
| Tobacco Cut Size                                   | (b) (4)                    |
| Characterizing Flavor                              | None                       |
| Rolling Paper Name                                 | Top gummed flat booklet    |
| Package Type                                       | Booklet                    |
| Package Quantity                                   | 2 booklets of 100 (papers) |
| Length   | 70 mm                      |
| Width  | 39 mm                      |
| Characterizing Flavor                              | None                       |
| <b>SE0000244: Real Gold 8 oz Large Bag</b>         |                            |
| Product Name                                       | TOP LITE CAN               |
| Package Type                                       | Can                        |
| Package Quantity                                   | 170.1 g                    |
| Tobacco Cut Size                                   | (b) (4)                    |
| Characterizing Flavor                              | None                       |
| Rolling Paper Name                                 | Top gummed flat booklet    |
| Package Type                                       | Booklet                    |
| Package Quantity                                   | 2 booklets of 100 (papers) |
| Length   | 70 mm                      |
| Width  | 39 mm                      |
| Characterizing Flavor                              | None                       |
| <b>SE0000252: Real Silver 3 oz Medium Bag</b>      |                            |
| Product Name                                       | GAM/ULTLTE, 36 BAGS/CASE   |
| Package Type                                       | Bag                        |
| Package Quantity                                   | 170.1 g                    |
| Tobacco Cut Size                                   | (b) (4)                    |
| Characterizing Flavor                              | None                       |

TPL Review for SE0000169, SE0000171, SE0000187, SE0000188, SE0000197, SE0000207, SE0000230, SE0000231, SE0000244, SE0000252

The predicate tobacco products are roll-your-own (RYO) tobacco and rolling paper/tobacco co-packages manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 16, 2011, Top Tobacco L.P. submitted 10 Substantial Equivalence (SE) Reports for the products listed above. FDA acknowledged the reports on September 21, 2011. FDA issued Advice/Information Request (A/I) letters and responses were submitted on the following days:

- November 8, 2012: for SE0000169, SE0000171, SE0000187, SE0000188, and SE0000197
  - Response to the A/I letter were submitted by the applicant on December 5, 2012 (SE0005264, SE0005284, SE0005261, SE0005279, SE0005254)
- November 29, 2012: for SE0000207 and SE0000230-SE0000231
  - Response to the A/I letter were submitted by the applicant on December 21, 2012 (SE0005519, SE0005529, SE0005528)
- December 13, 2012: for SE0000244 and SE0000252
  - Response to the A/I letter were submitted by the applicant on January 9, 2013 (SE0005868, SE0005876)

In response to FDA's November 8, 2012 A/I letter, the applicant's amendment clarified that the products subject to the ten SE Reports were not marketed after February 15, 2007 but prior to March 22, 2011. Thus, these SE reports are classified as regular SE Reports. Following these amendments on January 29, 2014, FDA received an amendment (SE0010147) in response for additional information request to uniquely identify the products for SE0000169, SE0000187, SE0000188, SE0000207, SE0000230, SE0000231, and SE0000244. On February 18, 2014, FDA received an amendment (SE0010202) containing a response to FDA's request for clarification of the predicate tobacco product names. On February 19, 2014, (SE0010211, SE0010212, SE0010213, SE0010214, and SE0010215) and March 4, 2014, (SE0010255) FDA received amendments which contained information seeking to demonstrate that the predicate products were commercially marketed in the United States as of February 15, 2007. FDA issued an A/I letter on May 7, 2015. In response, the applicant submitted amendment (SE0012047) on July 2, 2015. FDA issued a Preliminary Finding (PFind) letter on August 19, 2016. In response, the applicant submitted amendment (SE0013704) on September 14, 2016. On November 1, 2016, the applicant submitted amendment (SE0013735) in response to an information request. FDA issued another Preliminary Finding (PFind) letter on May 22, 2017. In response, the applicant submitted amendment (SE0014136 for all STNs) on June 5, 2017.

| Product Name                 | SE Report | Amendments   |
|------------------------------|-----------|--|
| Real Menthol 3 oz Medium Bag | SE0000169 | SE0005264<br>SE0010147<br>SE0010202<br>SE0010213<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |

|                                 |           |  |
|---------------------------------|-----------|--|
| Real Silver 8 oz Large Bag      | SE0000171 | SE0005284<br>SE0010202<br>SE0010211<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136              |
| Top Turkish 0.6 oz Pouch        | SE0000187 | SE0005261<br>SE0010147<br>SE0010202<br>SE0010212<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |
| Top Turkish 6 oz Canister       | SE0000188 | SE0005279<br>SE0010147<br>SE0010202<br>SE0010214<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |
| Real Menthol 8 oz Large Bag     | SE0000197 | SE0005254<br>SE0010202<br>SE0010213<br>SE0010255<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |
| Real Full Flavor 8 oz Large Bag | SE0000207 | SE0005519<br>SE0010147<br>SE0010202<br>SE0010214<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |
| Real Gold 3 oz Medium Bag       | SE0000230 | SE0005529<br>SE0010147<br>SE0010202<br>SE0010215<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136 |

|                                  |           |   |
|----------------------------------|-----------|---|
| Real Full Flavor 3 oz Medium Bag | SE0000231 | SE0005528<br>SE0010147<br>SE0010202<br>SE0010214<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136              |
| Real Gold 8 oz Large Bag         | SE0000244 | SE0005868<br>SE0010147<br>SE0010202<br>SE0010215<br>SE0012047<br>SE0013704<br>SE0013724<br>SE0013735<br>SE0014136 |
| Real Silver 3 oz Medium Bag      | SE0000252 | SE0005876<br>SE0010202<br>SE0010211<br>SE0012047<br>SE0013704<br>SE0013735<br>SE0014136                           |

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Idara Udoh, Marcella White, La'Shelle Tatum, and Kristen Jackson on September 22, 2011 (SE0000169, SE0000171, SE0000187, SE0000197, SE0000207, SE0000230, SE0000231, SE0000244, and SE0000252), September 23, 2011 (SE0000188), November 8, 2012 (SE0000169, SE0000171, SE0000187, SE0000188, and SE0000197), November 29, 2012 (SE0000207, SE0000230, and SE0000231), December 13, 2012 (SE0000244 and SE0000252) and March 8, 2013 (all STNs listed above).

The final reviews conclude that the SE Reports are administratively complete.

## 3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated March 5, 2014, conclude

that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are 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 August XX, 2017, concludes that the new tobacco products are 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 Tricia Johnson on May 30, 2014, and August 28, 2015, and Shixia Feng on November 2, 2016.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The new tobacco products have the following key differences in product composition compared to the predicate tobacco products:

- (b) (4) in all of the amounts of (b) (4) content in the new tobacco products SE0000169, SE0000171, SE0000197, SE0000207, SE0000230, SE0000231, SE0000244, and SE0000252 and overall (b) (4) in tobacco ingredients (b) (4)
- (b) (4) (SE0000187 and SE0000188) (b) (4) in (b) (4) and (b) (4) tobacco and (b) (4) (b) (4) in (b) (4) tobacco, but overall (b) (4) in tobacco ingredients (b) (4)
- All of the new tobacco products contained (b) (4) of certain casings and flavor additives as compared to the corresponding predicate tobacco products
- (b) (4) in the following additives in the new tobacco products in SE0000187 and SE0000188:
  - Addition of (b) (4), and denatured (b) (4) to tobacco filler (b) (4)
  - (b) (4) levels of (b) (4) and (b) (4) to tobacco filler (b) (4)

The (b) (4) in tobacco (b) (4) in all of the amounts of (b) (4) tobacco types did not change the relative proportions of the various types of tobacco for all STNs except SE0000187 and SE0000188. For all STNs except SE0000187 and SE0000188, the (b) (4) in tobacco (b) (4) of tobacco blend is related to a (b) (4) in the additives, including casings and flavorings, in the new tobacco products, and moisture in tobacco blend, which did not yield changes in the HPHC yields of cigarettes prepared from the new tobacco products as compared to the predicate tobacco products. The new and

corresponding predicate tobacco products do not differ significantly in relative quantities of individual tobacco types, and there were no changes in the HPHC yields; therefore the (b) (4) in all of the amounts of (b) (4) tobacco content in the new tobacco products does not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

In SE0000187 and SE0000188, there is a (b) (4) in (b) (4) tobacco and an (b) (4) of (b) (4) tobacco. Even though there is a large (b) (4) in the relative proportion of (b) (4) tobacco compared to the other types of tobacco, when compared to the tobacco quantities for SE0000187 and SE0000188, the (b) (4) in (b) (4) tobacco (b) (4) the total mass of the tobacco filler (b) (4) by only (b) (4) which is relatively minor and the overall amount of tobacco (b) (4) of tobacco has (b) (4)

The changes to the tobacco blend and addition or increases in additives in SE0000187 and SE0000188 may cause an (b) (4) in HPHCs. To address this concern, the applicant provided two sets of HPHC measurements; one set measured the content in the tobacco filler and the other the HPHC yield in the cigarette smoke from cigarettes prepared from the new and predicate products. The levels of HPHCs in the tobacco fillers of the new tobacco products demonstrated an increase in TSNAs. However, all of the HPHC yields in the cigarette smoke in cigarettes prepared from the new tobacco products were found to be equivalent or (b) (4) than the predicate tobacco products, demonstrating that the differences in the new tobacco products in SE0000187 and SE0000188 do not raise different questions of public health.

All of the SE Reports also indicate the reduction or elimination of the many flavorings and casing additives from the new tobacco products compared to the predicate tobacco products. The changes may cause (b) (4) in HPHCs due to the relative changes in tobacco (b) (4) when compared to the amount of tobacco (b) (4) used in the predicate products. However, the amounts of the additives removed from the new tobacco products were relatively small when compared to the total tobacco in the cigarettes and the changes did not yield changes in the HPHC yields of cigarettes prepared from the new tobacco products as compared to the predicate tobacco products. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

#### 4.2. ENGINEERING

Engineering reviews were completed by James Melchior on May 29, 2014, and Julie Morabito on August 18, 2015, and November 9, 2016<sup>1</sup>.

The final engineering review concludes that the new tobacco products have different characteristics related to product design compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions

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<sup>1</sup> A correction to the review was included in the file on January 18, 2017.

of public health. The new tobacco products have the following key differences in product design compared to the corresponding predicate tobacco products:

- SE0000187 and SE0000188: (b) (4) in cigarette paper base paper porosity

The (b) (4) cigarette paper base paper porosity in SE0000187 and SE0000188 may lead to differences in TNCO yields in cigarette smoke. The applicant provided smoke yield measurements of cigarettes prepared from the new tobacco products which are (b) (4) than or the same as the smoke yields of cigarettes prepared from the predicate tobacco products. Therefore, the differences in characteristics related to product design between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

#### 4.3. TOXICOLOGY

Toxicology reviews were completed by Luis Valerio on April 24, 2015, Maocheng Yang on July 25, 2016, and November 21, 2016.

The final toxicology review concludes that the new tobacco products have different characteristics related to toxicology compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The new tobacco products have the following key differences in product toxicology compared to the corresponding predicate tobacco products:

- (b) (4) TSNA levels in tobacco filler (SE0000169, SE0000171, SE0000187, SE0000188, SE0000197, SE0000207, SE0000231, and SE0000252)

Despite (b) (4) in TSNA levels in the tobacco filler of the new tobacco products in SE0000169, SE0000171, SE0000187, SE0000188, SE0000197, SE0000207, SE0000231, and SE0000252, levels of TSNA present in the smoke from cigarettes prepared from the new tobacco products did not (b) (4) when compared to the levels from cigarettes prepared from the corresponding predicate tobacco products. Therefore, the differences in characteristics related to toxicology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

#### 4.4. MICROBIOLOGY

Microbiology reviews were completed by Shanil Haugen on May 29, 2014, and Almaris Alonso on September 8, 2015, and November 22, 2016.

The final microbiology review concludes that the new tobacco products have different characteristics related to microbiology compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The new tobacco products have the following key differences related to product microbiology compared to the corresponding predicate tobacco products:

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- The new tobacco products are packaged in bags while the predicate tobacco products are packaged in canisters (SE0000169, SE0000197, SE0000207, SE0000230, SE0000231, and SE0000244)
- Reduction in the moisture in the new tobacco products compared to the predicate tobacco products (all SE Reports except SE0000207 and SE0000231)
- (b) (4) moisture content (less than or equal to (b) (4)) for SE0000207 and SE0000231

The final microbiology review concludes that the new tobacco products have different characteristics related to product microbiology compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. Six of the new products are packaged in resealable bags whereas their corresponding predicate products were packaged in cardboard canisters. A sealed bag is presumed to more effectively prevent moisture loss compared to a cardboard canister; however, moisture favors microbial growth. Although there are changes to packaging and moisture content, the moisture content was found to decrease over time (for all SE Reports except SE0000207 and SE0000231), which will reduce the microbial activity. For SE0000207 and SE0000231, the moisture content (b) (4) by (b) (4) however, given the small magnitude of this (b) (4) this change does not cause the new products to raise different questions of public health. The data the applicant provided related to moisture content adequately addressed the change in packaging from a microbiological point of view. Therefore, the differences in characteristics related to microbiology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

#### 4.5. SOCIAL SCIENCE

A social science review was completed by Sarah Johnson on June 4, 2014. An addendum was prepared on MONTH day YEAR, by REVIEWER to clarify the June 4, 2014 review.

The social science review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following differences between the new and predicate products:

- (b) (4) in tobacco filler mass (package quantity) by (b) (4) for SE0000169, SE0000230, SE0000231, SE0000252
- (b) (4) in tobacco filler mass (package quantity) by (b) (4) for SE0000171, SE0000197, SE0000207, SE0000244
- The new tobacco products are packaged without rolling papers while the predicate tobacco products are packaged with rolling papers (SE0000169, SE0000197, SE0000207, SE0000230, SE0000231, and SE0000244)

The addendum review states that although there is no currently available direct scientific evidence on the influence of RYO package quantity on consumer perception and use, other scientific evidence suggests that in certain circumstances such changes may impact consumer perception or use. Specifically, differences in package quantity may, in some cases, reduce

barriers to initiation (e.g., decrease in package quantity may lower the price, or make the product easier to conceal), or make it more difficult for current users to quit (e.g., larger quantities may lead people to not worry about running out of product, or increase consumption); however, given the small magnitude of these changes, these changes in package quantity do not cause the new products to raise different questions of public health.

With respect to the removal of the rolling papers, further clarification to the first Social Science review is warranted. I find that there is no currently available Social Science-related evidence that the removal of rolling papers would impact perception or use. Therefore, given the likelihood that the removal of rolling papers would not change the behavior of the user, this difference between the new and predicate products does not cause the new tobacco products to raise different questions of public health.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

The applicant submitted a health information summary. FDA has determined that statements provided for these SE Reports which are required in a health information summary pursuant to section 910(a)(4) of the FD&C Act do not constitute modified risk claims. The applicant's health information summary for each new tobacco product does not potentially violate section 911.

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 5, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 5, 2017.

## 6. CONCLUSION AND RECOMMENDATION

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

- (b) (4) in all of the amounts of (b) (4) tobacco content in the new tobacco products SE0000169, SE0000171, SE0000197, SE0000207, SE0000230,

- SE0000231, SE0000244, and SE0000252 and overall (b) (4) in tobacco ingredients (b) (4)
- (b) (4) (SE0000187 and SE0000188) (b) (4) in (b) (4) tobacco and (b) (4) in (b) (4), but overall (b) (4) in tobacco ingredients (b) (4)
- Addition of (b) (4) (SE0000187 and SE0000188)
- (b) (4) levels of (b) (4) (SE0000187 and SE0000188)
- Addition of (b) (4) (SE0000187 and SE0000188)
- All of the new tobacco products contained (b) (4) of certain casings and flavor additives as compared to the corresponding predicate tobacco products
- (b) (4) in tobacco filler mass (SE0000169, SE0000230, SE0000231, and SE0000252)
- (b) (4) in tobacco filler mass (SE0000171, SE0000197, SE0000207, and SE0000244)
- (b) (4) in cigarette paper base paper porosity (SE0000187 and SE0000188)
- (b) (4) TSNA levels in tobacco filler (SE0000169, SE0000171, SE0000187, SE0000188, SE0000197, SE0000207, SE0000231, and SE0000252)
- Change in packaging: canister to bag (SE0000169, SE0000197, SE0000207, SE0000230, SE0000231, and SE0000244)
- (b) (4) in the moisture in the new tobacco products compared to the predicate tobacco products (All SE Reports except SE0000207 and SE0000231)
- (b) (4) moisture content (b) (4) (SE0000207 and SE0000231)
- Removal of rolling paper (SE0000169, SE0000197, SE0000207, SE0000230, SE0000231, and SE0000244)

The applications contain sufficient information to determine that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant stated that there were differences in the tobacco blend, ingredients other than tobacco, cigarette paper base paper porosity and measured HPHCs in the tobacco filler between the new and predicate tobacco products. The applicant produced and tested cigarettes prepared from the new and predicate products. The measured HPHC values were found to be equivalent or below the levels in the cigarettes prepared from the predicate tobacco products and therefore, these differences between the new and predicate products do not cause the new tobacco products to raise different questions of public health. In SE0000171, SE0000197, SE0000207, and SE0000244, the applicant also identified differences in tobacco filler mass (b) (4) and in SE0000169, SE0000230, SE0000231, SE0000252 the identified differences in tobacco filler mass (b) (4). However, given the small magnitude of the changes, the differences in package quantity do not cause the new products to raise different questions of public health. The applicant also states that the new products were packaged without the inclusion of rolling paper in the packaging as compared to the predicate tobacco product packaging (SE0000169, SE0000197, SE0000207, SE0000230, SE0000231, and SE0000244). Given the likelihood that the removal of rolling papers would not change the behavior of the user, this difference between the new and predicate products does not cause the new tobacco products to raise different questions of public health. Finally, the applicant states that the packaging materials changed (from canister to pouch) between the new and predicate tobacco products. The applicant has provided sufficient evidence regarding moisture over time which either (b) (4) by a change of such small magnitude that it would not raise different questions of public health or has decreased which in turn would decrease the amount of

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microbial growth. Because moisture content can be affected by packaging changes and the moisture content was determined to not cause the new product to raise different questions of public health, the packaging changes do not cause the new products to raise different questions of public health. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

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

SE order letters should be issued for the new tobacco products in SE0000169, SE0000171, SE0000187, SE0000188, SE0000197, SE0000207, SE0000230, SE0000231, SE0000244, and SE0000252, as identified on the cover page of this review.