





**Technical Project Lead (TPL) Review: SE0011034 – SE0011038, SE0011040, and SE0011042-SE0011044**

<b>SE0011034: Longhorn Fine Cut Natural, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>
<b>SE0011035: Longhorn Fine Cut Wintergreen, 408.24 g</b>	
Package Type	Plastic can and lid
Package Quantity	408.24 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011036: Longhorn Fine Cut Wintergreen, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011037: Longhorn Long Cut Natural, 408.24 g</b>	
Package Type	Plastic can and lid
Package Quantity	408.24 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>
<b>SE0011038: Longhorn Long Cut Natural, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>

<sup>1</sup> Cuts per inch (CPI)

<sup>2</sup> As provided by the applicant's certification statement.

<sup>3</sup> The characterizing flavor is identified as "natural" in the May 12, 2015, amendment (SE0011760). The applicant defines "natural" as "no flavor."

<b>SE0011040: Longhorn Long Cut Straight, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Straight <sup>2,4</sup>
<b>SE0011042: Longhorn Long Cut Wintergreen, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011043: Longhorn Long Cut Mint, 408.24 g</b>	
Package Type	Plastic can and lid
Package Quantity	408.24 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Mint <sup>2</sup>
<b>SE0011044: Longhorn Long Cut Mint, 204.12 g</b>	
Package Type	Plastic can and lid
Package Quantity	204.12 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Mint <sup>2</sup>
<b>Common Attributes of SE Reports</b>	
Applicant	Swedish Match USA, Inc.
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Moist Snuff
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

<sup>4</sup> The characterizing flavor is identified as "straight" in the May 12, 2015, amendment (SE11760). The applicant states that straight is how the industry describes products which impart a "cool/sweet" taste.

**Technical Project Lead (TPL):**

Digitally signed by Colleen K. Rogers -S  
Date: 2018.11.02 17:22:15 -04'00'

Colleen K. Rogers, Ph.D.  
Director  
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)

Digitally signed by Matthew R. Holman -S  
Date: 2018.11.05 09:00:43 -05'00'

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

## TABLE OF CONTENTS





<b>1. BACKGROUND .....</b>	<b>5</b>
1.1. PREDICATE TOBACCO PRODUCTS .....	5
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	6
1.3. SCOPE OF REVIEW.....	8
<b>2. REGULATORY REVIEW .....</b>	<b>8</b>
<b>3. COMPLIANCE REVIEW .....</b>	<b>8</b>
<b>4. SCIENTIFIC REVIEW .....</b>	<b>9</b>
4.1. SOCIAL SCIENCE.....	9
<b>5. ENVIRONMENTAL DECISION.....</b>	<b>10</b>
<b>6. CONCLUSION AND RECOMMENDATION .....</b>	<b>11</b>

## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

<b>SE0011034: Longhorn Fine Cut Natural, 204.12 g</b>	
Product Name	Longhorn Fine Cut Natural 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>
<b>SE0011035: Longhorn Fine Cut Wintergreen, 408.24 g</b>	
Product Name	Longhorn Fine Cut Wintergreen 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011036: Longhorn Fine Cut Wintergreen, 204.12 g</b>	
Product Name	Longhorn Fine Cut Wintergreen 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011037: Longhorn Long Cut Natural, 408.24 g</b>	
Product Name	Longhorn Long Cut Natural 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>
<b>SE0011038: Longhorn Long Cut Natural, 204.12 g</b>	
Product Name	Longhorn Long Cut Natural 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI <sup>1</sup>
Characterizing Flavor	Natural <sup>2,3</sup>

<b>SE0011040: Longhorn Long Cut Straight, 204.12 g</b>	
Product Name	Longhorn Long Cut Straight
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Straight <sup>2,4</sup>
<b>SE0011042: Longhorn Long Cut Wintergreen, 204.12 g</b>	
Product Name	Longhorn Long Cut Wintergreen 34.02 g
Package Type	Plastic can and lid
Package Quantity	34.02 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Wintergreen <sup>2</sup>
<b>SE0011043: Longhorn Long Cut Mint, 408.24 g</b>	
Product Name	Longhorn Long Cut Mint
Package Type	Plastic can and lid
Package Quantity	37.42 grams
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Mint <sup>2</sup>
<b>SE0011044: Longhorn Long Cut Mint, 204.12 g</b>	
Product Name	Longhorn Long Cut Mint
Package Type	Plastic can and lid
Package Quantity	37.42 g
Tobacco Cut Size	 CPI <sup>1</sup>
Characterizing Flavor	Mint <sup>2</sup>

The predicate tobacco products are loose moist snuff smokeless tobacco products manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received nine SE Reports on March 24, 2015, from Swedish Match North America, Inc designated as Product Quantity Change SE Reports by the applicant. FDA issued Acknowledgement letters on April 17, 2015. On May 5, 2015, and May 7, 2015, FDA held teleconferences with the applicant to request additional product identification information and revised certification statements. On May 12, 2015, FDA received an amendment (SE0011760) with the requested information. On September 7, 2017, FDA received a general correspondence from the applicant (TC0002691) informing FDA of an organizational restructure and company name change from Swedish Match North America, Inc to Swedish Match USA, Inc. FDA issued a Preliminary Finding letter (PFind) for environmental assessment issues for SE0011034, SE0011037, SE0011038, SE0011040, and SE0011042-SE0011044 on February 13, 2018. On March 14, 2018, FDA received an amendment (SE0014586) responding to the February 13, 2018, PFind letter. On May 18, 2018, FDA held a teleconference with the applicant to request tobacco cut size information for SE0011035 and SE0011036. On May 31, 2018, FDA

received an amendment (SE0014742) with the requested information for SE0011035 and SE0011036. In the original applications, the applicant designated the reports as Product Quantity Change SE Reports, and included certification statements to reflect that the only difference between the new and corresponding predicate tobacco products is the product quantity change. During review, FDA found differences in the container-closure system composition and packaging configuration between the new and corresponding predicate tobacco products in all SE Reports. The applicant states that the new tobacco products are packaged with an empty can placed inside the container-closure system that consumers can refill themselves. Since the differences between the new and corresponding predicate tobacco products are not limited to a difference in product quantity, FDA reclassified the SE Reports from Product Quantity Change SE Reports to full SE Reports.<sup>5</sup> On June 12, 2018, FDA issued an Advice/Information Request (A/I) letter requesting clarification of the packaging configuration of the empty can and a revised certification statement for SE0011034, SE0011037, SE0011038, SE0011040, and SE0011042-SE0011044. On June 13, 2018, FDA issued an A/I letter requesting clarification of the packaging configuration of the empty can and a revised certification statement for SE0011035 and SE0011036. On August 8, 2018, FDA received amendments (SE0014845 and SE0014847) responding to the June 2018 A/I letters. On October 24, 2018, FDA received an amendment (SE0014909) responding to the October 22, 2018, Request For Information letter sent by the Office of Compliance and Enforcement (OCE) requesting clarification of the predicate tobacco product names in SE0011043 and SE0011044. On October 30, 2018, FDA received an amendment (SE0014916) responding to an email from OCE requesting clarification of characterizing flavor for the predicate tobacco products in SE0011043 and SE0011044.

Product Name	SE Report	Amendments
Longhorn Fine Cut Natural, 204.12 g	SE0011034	SE0011760 SE0014586 SE0014845
Longhorn Fine Cut Wintergreen, 408.24 g	SE0011035	SE0011760 SE0014742 SE0014847
Longhorn Fine Cut Wintergreen, 204.12 g	SE0011036	
Longhorn Long Cut Natural, 408.24 g	SE0011037	SE0011760 SE0014586 SE0014845
Longhorn Long Cut Natural, 204.12 g	SE0011038	
Longhorn Long Cut Straight, 204.12 g	SE0011040	
Longhorn Long Cut Wintergreen, 204.12 g	SE0011042	
Longhorn Long Cut Mint, 408.24 g	SE0011043	SE0011760 SE0014586 SE0014845 SE0014909 SE0014916
Longhorn Long Cut Mint, 204.12 g	SE0011044	

<sup>5</sup> See June 11, 2018, TPL memorandum "Deficiencies related to packaging composition and configuration for Swedish Match USA, Inc."

### 1.3. SCOPE OF REVIEW

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

## 2. REGULATORY REVIEW

A regulatory review was completed by Idara Udoh on April 17, 2015.

The review concludes that the SE Reports were not administratively complete because the tobacco cut size (all STNs) and characterizing flavor (SE0011034, SE0011037, SE0011038, and SE0011040) of the new and predicate tobacco products were missing.

However, this information was provided during the scientific review process. Therefore, these SE Reports are now 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 products in SE0011043 and SE0011044 are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE review dated May 15, 2015,<sup>6</sup> concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products in SE0011043 and SE0011044 are eligible predicate tobacco products.

The predicate tobacco products in SE0011034 - SE0011038, SE0011040, and SE0011042 were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products in SE0011034 - SE0011038, SE0011040, and SE0011042 are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under	Date
SE0011034	Longhorn Fine Cut Natural 34.02 g	SE0000098	September 25, 2017
SE0011035	Longhorn Fine Cut Wintergreen 34.02 g	SE0000101	March 1, 2018
SE0011036	Longhorn Fine Cut Wintergreen 34.02 g	SE0000101	March 1, 2018
SE0011037	Longhorn Long Cut Natural 34.02 g	SE0000099	September 25, 2017
SE0011038	Longhorn Long Cut Natural 34.02 g	SE0000099	September 25, 2017
SE0011040	Longhorn Long Cut Straight	SE0003404	April 21, 2017
SE0011042	Longhorn Long Cut Wintergreen 34.02 g	SE0000100	September 25, 2017

OCE also completed reviews to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the

<sup>6</sup> Addendum reviews were completed on October 31, 2018, to clarify that the characterizing flavor of the predicate tobacco product is "mint." The addendum reviews do not change the conclusion of the initial grandfather determination dated May 15, 2015.

FD&C Act). The OCE reviews dated August 6, 2015; August 26, 2015; September 11, 2015; April 30, 2018; May 8, 2018; and October 25, 2018, conclude that the new tobacco products are in compliance with the FD&C Act.

#### 4. SCIENTIFIC REVIEW

The applicant states that all of the new tobacco products are packaged with an empty 34.02 gram can<sup>7</sup> that consumers can refill themselves thus, making the new tobacco product convenient to carry without disrupting the consumer's usual pattern of use. I note that the addition of the empty refillable can was not evaluated by the scientific reviewers so, as Technical Project Lead, I provide an evaluation here. The empty refillable can is wrapped in an 80-gauge orientated polypropylene film wrapper and placed within the container containing loose tobacco in the new tobacco products. Since the new tobacco product container is composed of the same type of plastic as the wrapper on the empty can (i.e., polypropylene), any effect of the plastic on the tobacco (if any) from the wrapper would be the same as from the container. Furthermore, this small difference in plastic polymer does not cause the new tobacco products to raise different questions of public health with respect to leachables and extractables. Therefore, the addition of the empty refillable can does not cause the new tobacco products to raise different questions of public health.

Also, although not evaluated by the scientific reviewers, the applicant provided the composition of the new and predicate tobacco product container-closure systems in amendments SE0014586 and SE0014847. The predicate tobacco product cans are composed of (b) (4)

composed of high molecular weight hydrocarbons (polyolefins). Given the similarities of these plastics, we do not expect the small change in plastics to affect product stability. In addition, the majority of the container-closure system (i.e., the can/container) is composed of the same plastic in the new and corresponding predicate tobacco products. Consequently, in this particular case, the change from (b) (4) does not cause the new tobacco products to raise different questions of public health.

Scientific reviews were completed by the Office of Science (OS) for the following discipline:

##### 4.1. SOCIAL SCIENCE

Social science reviews were completed by Anh Nguyen on July 31, 2015, and by Katherine Margolis on August 24, 2018.

---

<sup>7</sup> The empty can has the same composition as the predicate tobacco product can: (b) (4)

The final social science review concludes that the new tobacco products have different characteristics from 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:

- The following changes in product quantity:
  - SE0011034, SE0011036, SE0011038, SE0011040, and SE0011042: Increase from 34.02 g to 204.12 g [500%]
  - SE0011035 and SE0011037: Increase from 34.02 g to 408.24 g [1100%]
  - SE0011043: Increase from 37.42 g<sup>8</sup> to 408.24 g [990%]
  - SE0011044: Increase from 37.42 g<sup>8</sup> to 204.12 g [445%]
- Change in packaging configuration from a single can full of loose moist snuff in the predicate tobacco products to a larger container that includes a wrapped, empty refillable can<sup>9</sup> in the new tobacco products

All the SE Reports indicate an increase in product quantity (445-1100%). The final social science review cites an Office of Science (OS) memorandum<sup>10</sup> that summarizes OS' determination that, at this time, changes in tobacco product quantity do not cause 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 review also evaluated the health information summary for each SE Report. FDA has determined that the health information summary provided for these SE Reports would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco products into interstate commerce.

## 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Susana Addo Ntim on February 9, 2018,<sup>11</sup> and May 11, 2018;<sup>11</sup> by Dilip Venugopal on May 24, 2018;<sup>12</sup> by Hoshing Chang on June 12, 2018; and by Susana Addo Ntim on September 26, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 24, 2018. The FONSI was supported by an environmental assessment prepared by FDA on October 24, 2018.

---

<sup>8</sup> The social science reviewer incorrectly listed the predicate tobacco product quantity as 34.02 g in the August 24, 2018, review.

<sup>9</sup> The composition of the empty can is identical to the composition of the predicate tobacco product can and it is wrapped in an 80-gauge orientated polypropylene film wrapper.

<sup>10</sup> See memorandum on product quantity changes, dated December 7, 2017.

<sup>11</sup> For SE0011034, SE0011037, SE0011038, SE0011040, and SE0011042-SE0011044 only.

<sup>12</sup> For SE0011035 and SE0011036 only.

## 6. CONCLUSION AND RECOMMENDATION

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

- The new tobacco products contain an empty refillable 34.02 g can<sup>9</sup> within the container containing loose tobacco
- Change of container-closure system lid material from (b) (4)
- SE0011034, SE0011036, SE0011038, SE0011040, and SE0011042: 500% increase in product quantity
- SE0011035 and SE0011037: 1100% increase in product quantity
- SE0011043: 990% increase in product quantity
- SE0011044: 445% increase in product quantity

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Since the empty refillable can wrapper is composed of the same type of plastic as the new tobacco product containers (polypropylene), this difference does not cause the new tobacco products to raise different questions of public health with respect to leachables and extractables, and any effect of the plastic on the tobacco (if any) from the wrapper would be the same as from the container. Therefore, the addition of the empty refillable can does not cause the new tobacco products to raise different questions of public health. For the change in container-closure system lid material, given the similarities of the plastics, we do not expect this small change in plastics to affect product stability. In addition, the majority of the container-closure system (i.e., the can/container) is composed of the same plastic in the new and corresponding predicate tobacco products. Consequently, in this particular case, the change from (b) (4) does not cause the new tobacco products to raise different questions of public health. All the SE Reports indicate an increase in product quantity from 445-1100%. The OS memorandum<sup>10</sup> concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion. 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 in SE0011043 and SE0011044 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The predicate tobacco products in SE0011034, SE0011035, SE0011036, SE0011037, SE0011038, SE0011040, and SE0011042 were previously determined to be substantially equivalent by FDA under SE0000098, SE0000101, SE0000099, SE0003404, and SE0000100.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0011034 was previously determined to be substantially equivalent by FDA under SE0000098. Comparison of the new tobacco product to the grandfathered product (Longhorn Fine Cut Natural 37.42 g) reveals that the new tobacco product has the following differences in characteristics from Longhorn Fine Cut Natural 37.42 g, the grandfathered tobacco product:<sup>13</sup>

- 445% increase in product quantity
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from (b) (4)
- 1% decrease in the amount of (b) (4)
- Reduction in the yields of many HPHCs

The differences in (b) (4) and HPHC yields listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000098. Therefore, these differences do not cause the new tobacco product in SE0011034 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container-closure system lid material between the new tobacco product in SE0011034 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011034 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco products in SE0011035 and SE0011036 were previously determined to be substantially equivalent by FDA under SE0000101. Comparison of the new tobacco products to the grandfathered product (Longhorn Fine Cut Wintergreen 34.02 g) reveals that the new tobacco products have the following differences in characteristics from Longhorn Fine Cut Wintergreen 34.02 g, the grandfathered tobacco product:<sup>14</sup>

- 1100% increase in product quantity in SE0011035
- 500% increase in product quantity in SE0011036
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from (b) (4)
- Reduction or minimal increases of no more than 4% in the yields of many HPHCs

The differences in HPHCs listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000101. Therefore, these differences do not cause the new tobacco products in SE0011035 and SE0011036 to raise different questions of public health.

---

<sup>13</sup> The tobacco cut size was incorrectly listed as (b) (4) CPI in FDA's SE orders for both the new and predicate tobacco products in SE0000098 issued on September 25, 2017. The orders were subsequently amended to correct the tobacco cut size to (b) (4) CPI on September 26, 2018. Therefore, there is no difference in tobacco cut size between the tobacco products in SE0000098 and SE0011034.

<sup>14</sup> The tobacco cut size was incorrectly listed as (b) (4) CPI in FDA's SE orders for both the new and predicate tobacco products in SE0000101 issued on March 1, 2018. The orders were subsequently amended to correct the tobacco cut size to (b) (4) CPI on September 26, 2018. Therefore, there is no difference in tobacco cut size between the tobacco products in SE0000101 and SE0011035 or SE0011036.

Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container-closure system lid material between the new tobacco products in SE0011035 and SE0011036 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0011035 and SE0011036 to the predicate or grandfathered tobacco product, the new tobacco products do not raise different questions of public health.

The predicate tobacco products in SE0011037 and SE0011038 were previously determined to be substantially equivalent by FDA under SE0000099. Comparison of the new tobacco products to the grandfathered product (Longhorn Long Cut Natural 37.42 g) reveals that the new tobacco products have the following differences in characteristics from Longhorn Long Cut Natural 37.42 g, the grandfathered tobacco product:

- 990% increase in product quantity in SE0011037
- 445% increase in product quantity in SE0011038
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from (b) (4)
- 4% increase in the amount of (b) (4)
- Reduction in the yields of many HPHCs

The differences in (b) (4) HPHCs listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000099. Therefore, these differences do not cause the new tobacco products in SE0011037 and SE0011038 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container-closure system lid material between the new tobacco products in SE0011037 and SE0011038 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0011037 and SE0011038 to the predicate or grandfathered tobacco product, the new tobacco products do not raise different questions of public health.

The predicate tobacco product in SE0011040 was previously determined to be substantially equivalent by FDA under SE0003404. Comparison of the new tobacco product to the grandfathered product (Longhorn Long Cut Straight) reveals that the new tobacco product has the following differences in characteristics from Longhorn Long Cut Straight, the grandfathered tobacco product:<sup>15</sup>

- 445% increase in product quantity in SE0011040
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from (b) (4)
- 25% decrease in NNN and NNK

---

<sup>15</sup> I note that the characterizing flavor is listed as "cool/sweet" for the grandfathered tobacco product in SE0003404 and as "straight" for the new tobacco product in SE0011040. The applicant states, "[t]he descriptor 'Straight' is how the industry describes and how consumers recognize products which impart a cool/sweet taste." Therefore, there is no difference in characterizing flavor between the tobacco products in SE0003404 and SE0011040.

- Increase in ammonia, arsenic, chromium, and nitrate by 16%, 82%, 15%, and 15%, respectively

The differences in NNN, NNK, ammonia, arsenic, chromium, and nitrate listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003404. Therefore, these differences do not cause the new tobacco product in SE0011040 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container-closure system lid material between the new tobacco product in SE0011040 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011040 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0011042 was previously determined to be substantially equivalent by FDA under SE0000100. Comparison of the new tobacco product to the grandfathered product (Longhorn Long Cut Wintergreen 37.42 g) reveals that the new tobacco product has the following differences in characteristics from Longhorn Long Cut Wintergreen 37.42 g, the grandfathered tobacco product:

- 445% increase in product quantity in SE0011042
- Addition of an empty refillable 34.02 g can within the container
- Change of container-closure system lid material from (b) (4)
- Reduction in the yields of many HPHCs

The differences in HPHCs listed above are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000100. Therefore, these differences do not cause the new tobacco product in SE0011042 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity, addition of the empty can, and change in container-closure system lid material between the new tobacco product in SE0011042 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011042 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act and I 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 SE0011034-SE0011038, SE0011040, and SE0011042-SE0011044, as identified on the cover page of this review.