



Technical Project Lead (TPL) Review:

SE0002649, SE0002651 and SE0015071

SE0002649: Oliver Twist Original, Chewing Tobacco Bits¹	
Package Type	Plastic container with an aluminum/plastic pouch
Package Quantity	7.0 g
Portion Mass	200 mg/bit
Portion Length	9.5 mm
Portion Width ²	4.6 mm
Portion Thickness ²	4.6 mm
Characterizing Flavor	None ³
SE0002651: Oliver Twist Original, Chewing Tobacco Bits¹	
Package Type	Aluminum/plastic pouch
Package Quantity	0.5 g ⁴
Portion Mass	200 mg/bit
Portion Length	9.5 mm
Portion Width ²	4.6 mm
Portion Thickness ²	4.6 mm
Characterizing Flavor	None ³
SE0015071: Oliver Twist Sunberry, Chewing Tobacco Bits¹	
Package Type	Aluminum/plastic pouch
Package Quantity	0.6 g ⁴
Portion Mass	240 mg/bit
Portion Length	9.5 mm
Portion Width ²	5.0 mm
Portion Thickness ²	5.0 mm
Characterizing Flavor	Sunberry

¹ Per amendments SE0015090 and SE0015106, tobacco bits are manufactured by (b) (4) and their (b) (4). Due to the natural variation in tobacco leaf size, the (b) (4) aspect of manufacture, and other typical aspects of manufacturing variation; tobacco bits vary in mass. Therefore, in this instance, the portion count is not needed because portion count is dictated by package quantity. For example, in SE0002649, the new and predicate products contain 7 g of product, regardless of the number of bits.

² Bits are cylindrical, width and thickness represent diameter.

³ The Oliver Twist Original variety does not have a characterizing flavor, noted with "none" in the description of SE0002649 per the May 14, 2018 Compliance Review Addendum.

⁴ The package quantity was calculated by FDA based on the average number of bits per pouch and the average mass of a single bit submitted by the applicant. For example, per amendment SE0015106, in SE0015071 90% of the products contain between 2 and 3 bits and the average mass of a bit is 240 mg $[(2 \text{ bits} \times 240 \text{ mg}) + (3 \text{ bits} \times 240 \text{ mg})] / 2 = 600 \text{ mg} (0.6\text{g.})$

Common Attributes of SE Reports	
Applicant	House of Oliver Twist A/S
Report Type	Provisional
Product Category	Smokeless Tobacco Product
Product Sub-Category	Portioned Chewing Tobacco (SE0002651 and SE0015071 as part of a smokeless tobacco co-package)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Melissa McCulloch -S	Digitally signed by Melissa McCulloch -S Date: 2019.03.29 10:22:20 -04'00'
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Melissa McCulloch, Ph.D.
Senior Regulatory Scientist
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: 2019.03.29 10:30:36 -04'00'

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 products:

SE0002649: Oliver Twist Original, Chewing Tobacco Bits	
Product Name	Oliver Twist Original ¹
Package Type	Plastic container with an aluminum/plastic pouch
Package Quantity	7.0 g
Portion Mass	200 mg/bit
Portion Length	9.5 mm
Portion Width ²	4.6 mm
Portion Thickness ²	4.6 mm
Characterizing Flavor	None ³
SE0002651: Oliver Twist Original, Chewing Tobacco Bits	
Product Name	Oliver Twist Multipack ¹
Package Type	Plastic container with 6 aluminum/plastic pouches
Package Quantity	3.0 g
Portion Mass	200-250 mg/bit ⁵
Portion Length	9.5 mm
Portion Width ²	4.6-5.0 mm ⁵
Portion Thickness ²	4.6-5.0 mm ⁵
Characterizing Flavor	Original ³ , Sunberry, Wintergreen, Tropical, Citrus, Mint
Additional Property	Variety pack of 6 flavors
SE0015071: Oliver Twist Sunberry, Chewing Tobacco Bits	
Product Name	Oliver Twist Multipack ¹
Package Type	Plastic container with 6 aluminum/plastic pouches
Package Quantity	3.0 g
Portion Mass	200-250 mg/bit ⁵
Portion Length	9.5 mm
Portion Width ²	4.6-5.0 mm ⁵
Portion Thickness ²	4.6-5.0 mm ⁵
Characterizing Flavor	Original ³ , Sunberry, Wintergreen, Tropical, Citrus, Mint
Additional Property	Variety pack of 6 flavors

The predicate tobacco products are portioned chewing tobacco, smokeless tobacco products manufactured by the applicant.

⁵ May vary by flavor

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 23, 2011, FDA received two Substantial Equivalence (SE) Reports from House of Oliver Twist A/S for a 7g portioned chewing tobacco product and a portioned chewing tobacco product co-package containing four flavors (SE0002649, SE0002651, respectively). For SE00002651, the Original and Sunberry flavors of the tobacco product are each a new tobacco product; the co-packaging does not result in a new tobacco product because the co-packaging does not modify the products, including their respective container closure systems. A separate STN was generated for the Sunberry flavor (SE0015071), and SE0002651 was assigned to the Original flavor in the co-packaged product.⁶ On August 30, 2011, FDA issued Acknowledgement letters. On January 31, 2013, FDA issued Advice/Information Request (A/I) letters. On September 6, 2012, FDA completed Public Health Impact (PHI) reviews and assigned the SE Reports to PHI Tier 1.

On March 4, 2013, in response to the A/I letters, FDA received amendments for SE0002649 and SE0002651 (SE0007673 and SE0007671, respectively). On May 7, 2013, FDA completed a second round of PHI reviews for these SE Reports. FDA assigned the SE Reports to PHI Tier 2. On March 5, 2014, FDA issued a Correction letter noting a change to the tobacco product names on record based on information received from the applicant after receipt of the SE Reports.

On December 11, 2014, FDA issued a Notification letter for the SE Reports indicating scientific review would begin on January 25, 2015. On December 17, 2014, FDA conducted a telecon to request the applicant provide additional information to uniquely identify the new and predicate tobacco products, including package type, package quantity, unit size, length, width, and thickness.⁷ On December 18, 2014, FDA received an unsolicited amendment confirming receipt of the December 11, 2014 Notification letter (SE0010799). On January 9, 2015, FDA received an amendment (SE0010827) in response to the December 17, 2014 information request. On January 13, 2015 and January 21, 2015, FDA conducted telecons to clarify the number of bits in each pack and multipack pouch of the new and predicate tobacco products.

On January 20, 2015, and January 26, 2015, FDA received responses to the January 13, 2015 and January 21, 2015 information requests for SE0002649 and SE0002651 (SE0010837 and SE0010848, respectively). On May 15, 2015, FDA issued an A/I letter. On July 6, 2015, FDA received the response to the A/I letter (SE0012045).

On December 23, 2015, FDA issued a Preliminary Finding (PFind) letter. On January 21, 2016, FDA received the response to the PFind letter, which included a request for categorical exclusion (SE0012798). On March 8, 2016 (email communication) and March 14, 2016 (teleconference), FDA asked the applicant to provide clarification on information provided in amendment SE0012798 (e.g., target specifications for several parameters, ingredient quantities, HPHC testing, and flavor specifications).

On March 23, 2016, FDA received the response to our March 8, 2016 and March 14, 2016 information requests (SE0013019). On April 7, 2016, FDA held a teleconference requesting clarification on the information provided in SE0013019 regarding the use of black currant flavor in

⁶ For additional information, please refer to the March 27, 2019 Regulatory Review.

⁷ The December 23, 2015, Memo to file documents that communicating with the applicant via teleconference after issuance of the Notification letter to request additional information to uniquely identify the new tobacco products is a deviation from our processes/policy.

the new and predicate tobacco products in SE0002651. On April 20, 2016, FDA received an amendment for SE0002651 in response to our April 7, 2016 information request (SE0013314).

On November 6, 2018, FDA held a teleconference requesting confirmation that the new and predicate products for the Wintergreen and Tropical products in SE0002651 are identical. On November 13, 2018, FDA received an amendment for SE0002651 in response to the November 6, 2018 information request (SE0014952), which provided that confirmation to FDA.

SE0002651 was submitted as a co-package containing four tobacco products. On January 28, 2019 FDA created a new STN (SE0015071) for the Sunberry flavor.⁶ On February 21, 2019 and March 1, 2019 FDA received amendments, SE0015090 (for SE0002649) and SE0015106 (for SE0002651 and SE0015071), containing clarifying product information. FDA issued an Acknowledgement letter for SE0015071 and a correction letter for SE0002651 on March 27, 2019.

Product Names	SE Report	Amendments
Oliver Twist Original, Chewing Tobacco Bits	SE0002649	SE0007673 SE0010799 SE0010827 SE0010837 SE0012045 SE0012798 SE0013019 SE0015090
Oliver Twist Original, Chewing Tobacco Bits	SE0002651	SE0007671 SE0010799 SE0010827 SE0010848 SE0012045 SE0012798 SE0013019 SE0013314 SE0014952 SE0015106
Oliver Twist Sunberry, Chewing Tobacco Bits	SE0015071	SE0007671 SE0010799 SE0010827 SE0010848 SE0012045 SE0012798 SE0013019 SE0013314 SE0014952 SE0015106

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 on January 31, 2013, and June 11, 2013. The SE Reports were found to be administratively incomplete. The final reviews conclude that the SE Reports are not administratively complete because the following information is not included in the SE Reports:

1. Heating source of the new and predicate tobacco products
2. Environmental assessment⁸

This information was provided during the scientific review process. Therefore, these 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated February 13, 2015⁹, 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.

4. SCIENTIFIC REVIEW

Oliver Twist Original Chewing Tobacco Bits (0.5 g) and Oliver Twist Sunberry Chewing Tobacco Bits (0.6 g) are referred to below under one STN, SE0002651 which was originally issued for a 2.0 g multipack containing Original, Sunberry, Tropical and Wintergreen flavor varieties. The Sunberry flavor was issued a new STN (SE0015071) after the scientific reviews were completed. Any mention of Sunberry in section 4 of this review pertains to SE0015071.⁶ Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Jiu Ai on April 23, 2015, by An Vu on August 28, 2015, and by Christina Young on April 28, 2016.

⁸ The applicant did not submit an environmental assessment; however, they submitted a claim for categorical exclusion for all SE Reports (SE0012798).

⁹ Addendum reviews were completed on February 19, 2015, to correct an email address for the applicant's point of contact. Additional addendum reviews were completed on May 14, 2018, to add a characterizing flavor. The addendum reviews do not change the conclusions of the initial grandfather determinations dated February 13, 2015.

The final chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products. The review concludes that the differences do not cause the new tobacco product in SE0002649 to raise different questions of public health, but SE0002651 lacks adequate evidence to demonstrate that the differences do not cause the new tobacco product to raise different questions of public health. The review identifies the following deficiency that has *not* been adequately resolved:

1. SE0002651 states that Oliver Twist Sunberry in the new and predicate products differ in ingredients. More specifically, all of the ingredients and ingredient quantities are the same except (b) (4) flavor is from a different supplier in the new and predicate products. Your SE Report does not include adequate evidence to demonstrate that addition of (b) (4) does not cause the new product to raise different questions of public health. Your SE Report cites EU findings regarding this ingredient, but the findings do not relate to the safety of the ingredient. Provide adequate scientific and evidence to demonstrate that addition of (b) (4) concentrate does not cause the new product to raise different questions of public health.

Therefore, the review concludes that the applicant did not demonstrate that the differences in characteristics between the new and predicate tobacco products in SE0002651 do not cause the new tobacco product to raise different questions of public health from a chemistry perspective. However, based upon the toxicology review of this deficiency, as technical project lead, I conclude that this deficiency was identified in error and should not be communicated to the applicant.

The applicant submitted amendments SE0013019 and SE0013314 in response to the PFind letter issued on December 23, 2015. In these amendments, the applicant submits that the supplier of (b) (4) flavor for Oliver Twist Sunberry (SE0002651) is different for the new and predicate tobacco products. The formula of the (b) (4) flavor in the new tobacco product contains (b) (4) of (b) (4) ((b) (4) of the total product), which is not present in the predicate tobacco product.

The applicant states that both the new and predicate tobacco products contain the same amount of (b) (4) flavor (b) (4) unit of product use). The applicant states that (b) (4) (b) (4) flavor is a complex ingredient of which (b) (4) is a component added at (b) (4) of the total formulation for both the new and predicate tobacco products. The new and predicate tobacco product portions range from (b) (4). Therefore, the amount of (b) (4) is (b) (4)/unit of product use, which corresponds to between (b) (4) and (b) (4) of the total product mass. (b) (4) and (b) (4) are (b) (4) d from (b) (4) and these food products are considered safe for human consumption by the oral route. Thus, the addition of (b) (4) specifically the small amount (b) (4) (b) (4) (b) (4) of the total product) (b) (4) added to the new tobacco product in SE0002651 does not cause the new tobacco product to raise different questions of public health. A more detailed evaluation of this deficiency is contained in the toxicology discussion, Section 4.3.

The new and predicate tobacco products in SE0002649 are Oliver Twist Original flavor. The new and predicate tobacco products in SE0002651 are a variety pack containing Oliver Twist Original flavor as one of the flavor varieties. The applicant submits tobacco blend, ingredient and HPHC information for SE0002649, which also applies to the Oliver Twist Original flavor variety in SE0002651. Therefore, all evaluations of SE0002649 also apply to the Oliver Twist Original flavor variety in SE0002651. The reviews identified the following differences in the new tobacco product compared with the predicate tobacco product for SE0002649 and the flavor variety Oliver Twist Original in SE0002651:

- Increased total and free nicotine
- (b) (4) increase in (b) (4) ingredients¹⁰
- Removal of (b) (4) ingredient¹⁰
- Change from (b) (4) tobacco to (b) (4) tobacco¹⁰

With respect to the increased total and free nicotine in the new tobacco product compared to the predicate tobacco product in SE0002649 and the flavor variety Oliver Twist Original in SE0002651, the average of all nicotine mean values across all production years for the new and predicate tobacco product are 31.5 mg/g and 27 mg/g, respectively. This difference results in a 17% higher average quantity of total nicotine in the new tobacco product compared with the predicate tobacco product. The average of all free nicotine values across all production years is 0.04 and 0.02 for the new and predicate tobacco products, respectively. This difference results in a 100% higher average quantity of free nicotine in the new tobacco product compared with the predicate tobacco product. However, the absolute quantities of total and free nicotine are small. Therefore, the increases in total and free nicotine do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

The new tobacco product in SE0002649 and the flavor variety Oliver Twist Original in SE0002651 contain an (b) (4) higher amount of (b) (4) ingredients compared with the predicate tobacco product. (b) (4) contains (b) (4). Large doses of (b) (4) in (b) (4) can lead to hypokalemia and serious hypertension, a syndrome known as hypermineralo-corticoidism. The applicant provided information to establish that the amount of (b) (4) in the new and corresponding predicate tobacco products are identical. Thus, the increased amount of (b) (4) flavor ingredients does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

The removal of (b) (4) ingredient from the new tobacco product in SE0002649 and the flavor variety Oliver Twist Original in SE0002651 does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

The applicant provided tobacco specific nitrosamine (TSNA) and benzo[a]pyrene (B[a]P) data for the new and predicate tobacco products in SE0002649 and the Oliver Twist Original variety in SE0002651. All TSNA and B[a]P values in the new tobacco product are comparable or lower compared to the predicate tobacco product, which supports that the change from (b) (4) to (b) (4) does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

¹⁰ These differences were contained in the first chemistry review but not captured in the final chemistry review.

The applicant submits that in SE0002651, the new and corresponding predicate tobacco products for the flavor varieties Oliver Twist Tropical and Oliver Twist Wintergreen are identical. The reviews identified the following differences in the new tobacco products in SE0002651 compared with the corresponding predicate tobacco products:

- The new tobacco product is a variety pack that does not contain two of the flavor varieties present in the predicate tobacco product: Oliver Twist Citrus and Oliver Twist Mint
- The outer packaging material changed from plastic to paper¹⁰
- In the Oliver Twist Sunberry flavor variety, flavor (b) (4) is sourced from different suppliers and the formula in the new tobacco product contains (b) (4) of (b) (4) (b) (4) of the total product), which is not present in the predicate tobacco product

The removal of (b) (4) and (b) (4) flavor varieties in the new tobacco product in SE0002651 does not cause the new tobacco product to raise different questions of public health from a chemistry perspective. Additionally, the change of packaging material from plastic to paper in the new tobacco product in SE0002651 is located on the outer container which has no direct contact with the tobacco products; this change does not cause the new tobacco product to raise different questions of public health from a chemistry perspective. The (b) (4) flavor ingredient differences in Oliver Twist Sunberry are discussed above and do not cause the new product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by James Cheng on April 10, 2015, August 27, 2015 and April 05, 2016.

The final engineering review concludes that the new tobacco products have different characteristics related to product engineering 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 review identified the following differences:

- SE0002649 and the Oliver Twist Original variety in SE0002651: composition (b) (4) and (b) (4) flavorings and suppliers)
- SE0002651: The new tobacco product is a variety pack that does not contain two of the flavor varieties present in the predicate tobacco product: Oliver Twist Citrus, and Oliver Twist Mint

The composition changes in both SE Reports and flavor variety changes in SE0002651 are addressed in the chemistry, toxicology and microbiology sections (4.1, 4.3 and 4.4) of this review. The engineering reviews focused on establishing the necessary design specifications of the new and predicate tobacco products. The applicant has adequately provided the necessary target specifications for final tobacco moisture, portion mass, portion length, portion width, and portion thickness. 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Ines Pagan on September 11, 2018.¹¹

The toxicology review concludes that the new tobacco product in SE0002651 has different characteristics related to product toxicology 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 difference:

- Oliver Twist Sunberry (in SE0002651): The addition of (b) (4) of (b) (4) (b) (4) to the ingredient (b) (4)

The applicant provided information to support that (b) (4) is generally recognized to be safe for human consumption according to the European Juice Association (AIJN), and its use is accepted by the European Union and national food inspections. Although this information pertains to ingestion of (b) (4) as food products, it is relevant to exposures via the oral route and can inform the toxicology evaluation of smokeless tobacco products. In general, (b) (4) and (b) (4) are made from (b) (4) and these food products are considered safe for human consumption by the oral route. (b) (4) and (b) (4) including (b) (4) are included in an FDA list of (b) (4) approved for human consumption stating the following: “under the jurisdiction of the Food and Drug Administration and are subsequently listed in the CFR Title 21; Subchapter B as ‘Food for Human Consumption,’ and are correspondingly classified as non-hazardous materials”. In summary, (b) (4) and (b) (4) are extracted from (b) (4) and these food products are considered safe for human consumption by the oral route. Thus, the addition of natural (b) (4) specifically the small amount (b) (4) (b) (4) of (b) (4) added to the Sunberry variety of the new tobacco product in SE0002651, does not cause the new tobacco product to raise different questions of public health from a toxicology perspective. Therefore, the differences in characteristics between the new and predicate tobacco products in SE0002651 do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

4.4. MICROBIOLOGY

Microbiology reviews were completed by Norma Duran on April 23, 2015, and by Colleen Rogers on August 24, 2015, and April 06, 2016.

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. The review identified the following difference:

¹¹ The toxicology review only evaluated SE0002651.

- The tobacco blend has changed from (b) (4) tobacco to (b) (4) tobacco

The new tobacco products contain (b) (4) tobacco whereas the predicate tobacco products contain (b) (4) tobacco. (b) (4) tobacco is characterized by high microbial activity (nitrate reduction) during curing and a high potential for mold contamination. The applicant adequately addressed this concern by submitting data to show the following:

- The new tobacco products have consistent microbial counts over the storage period, and these meet the applicant's internal standard of (b) (4)
- TSNA data show that TSNA are approximately (b) (4) lower in the new tobacco products compared to the corresponding predicate tobacco products
- Product processing has been modified so that the (b) (4) (b) (4) results in new tobacco products that have lower microbial counts than the corresponding predicate tobacco products
- The moisture content of the new tobacco products remains stable over the storage period

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 microbiology perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports (SE0002649, SE0002651 and SE0015071) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

SE0002649 and SE0002651 have the following key differences in characteristics between the new and predicate tobacco products:

- 17% increase in total nicotine values across all production years¹²
- 100% increase in free nicotine mean values across all production years¹²
- (b) (4) increase in (b) (4) flavor ingredients
- Removal of (b) (4) flavor ingredient
- The tobacco blend has changed from (b) (4) to (b) (4) tobacco

¹² The applicant submitted total and free nicotine for the Oliver Twist Original variety of the new tobacco products for three production years (2012, 2013 and 2014) and five production years for the corresponding predicate tobacco products (2003, 2004, 2005, 2006 and 2007).

- The outer packaging material changed from plastic to paper (SE0002651 only)

In addition to the differences noted above for SE0002649 and SE0002651, SE0015071 has the following key differences in characteristics between the new and predicate tobacco products:

- The outer packaging material changed from plastic to paper
- The flavor (b) (4) is sourced from a different supplier and the formula in the new tobacco product contains (b) (4) of (b) (4) (b) (4) of the total product), which is not present in the predicate tobacco product

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health.

Although there is a 17% increase in total nicotine and 100% increase in free nicotine mean values across all production years in SE0002649 and SE0002651, the absolute quantities of total and free nicotine are small. Therefore, the increases in total and free nicotine do not cause the new tobacco products to raise different questions of public health.

There is an (b) (4) increase in the (b) (4) flavor ingredients in SE0002649 and SE0002651 which could lead to increased glycyrrhizic acid. The applicant provided information to establish that the amount of (b) (4) in the new and corresponding predicate tobacco products are identical. Thus, the increased amount of (b) (4) flavor ingredients does not cause the new tobacco products to raise different questions of public health.

The removal of (b) (4) ingredient in SE0002649 and SE0002651 does not cause the new tobacco products to raise different questions of public health.

All TSNA's and B[a]P values for the new tobacco products in SE0002649 and SE0002651 are comparable or lower compared to the corresponding predicate tobacco products. Further, the new tobacco products have consistent microbial counts over the storage period which meet the applicant's internal standard of (b) (4). Additionally, product processing has been modified so (b) (4). Finally, the moisture content of the new tobacco products remains stable over the storage period. Consequently, the change from (b) (4) to (b) (4) does not cause the new tobacco products to raise different questions of public health.

The change of packaging material from plastic to paper in the new tobacco product of SE0002651 and SE0015071 is located on the outer container which has no direct contact with the tobacco products; this change does not cause the new tobacco product to raise different questions of public health. Finally, natural (b) (4) and (b) (4) are extracted from (b) (4), and these food products are considered safe for human consumption by the oral route. Therefore, the addition of (b) (4) of (b) (4) concentrate to the ingredient (b) (4) in SE0015071 does not cause the new tobacco product 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.

The predicate tobacco products 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).

Because the proposed action is issuing SE orders for the provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0002649, SE0002651, and SE0015071 as identified on the cover page of this review.