

Technical Project Lead (TPL) Review: SE0015598, SE0015599, SE0015601, SE0015602, SE0015603, and SE0015604

Anni-Color and Anni-C	B Wood Tip	
Package Type	Cello (polypropylene plastic wrap)	
Package Quantity	1 Cigar	
Length	126.9 mm	
Diameter	9.57 mm	
Tip	Wood	
Characterizing Flavor	None	
E0015599: Black & Mild® Ho	rizon Wood Tip	
Package Type	Cello (polypropylene plastic wrap)	
Package Quantity	1 Cigar	
Length	126.9 mm	
Diameter	9.57 mm	
Tip	Wood	
Characterizing Flavor	None	
E0015601: Black & Mild® Horizon		
Package Type	Cello (polypropylene plastic wrap)	
Package Quantity	1 Cigar	
Length	126.9 mm	
Diameter	9.57 mm	
Tip	Plastic	
Characterizing Flavor	None	
E0015602: Black & Mild® 808	3	
Package Type	Cello (polypropylene plastic wrap)	
Package Quantity	1 Cigar	
Length	126.9 mm	
Diameter	9.57 mm	
Tip	Plastic	
Characterizing Flavor	None	
E0015603: Black & Mild® Vin	yl Wood Tip	
Package Type	Cello (polypropylene plastic wrap)	
Package Quantity	1 Cigar	
Length	126.9 mm	
Diameter	9.57 mm	
Tip	Wood	
Characterizing Flavor	None	

SE0015604: Black & Mild® Vinyl			
Package Type	Cello (polypropylene plastic wrap)		
Package Quantity	1 Cigar		
Length	126.9 mm		
Diameter	9.57 mm		
Tip	Plastic		
Characterizing Flavor	None		
Common Attributes of SE Repo	mmon Attributes of SE Reports		
Applicant	John Middleton Co.		
Report Type	Regular		
Product Category	Cigar		
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar		
Recommendation			
Issue Substantially Equivalent (sue Substantially Equivalent (SE) orders.		

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S Date: 2020.04.21 11:59:47 -04'00'

Kenneth M. Taylor, Ph.D. Chemistry Branch Chief Division of Product Science

Signatory Decision:

\boxtimes	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: 2020.04.21 13:13:05 -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:

2 Mood Tin		
0015598: Black & Mild® 808 Wood Tip Product Name Black & Mild Apple		
Black & Mild Apple		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Apple		
E0015599: Black & Mild® Horizon Wood Tip		
Prince Albert Soft Cherry Vanilla		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Cherry Vanilla		
rizon		
Prince Albert Soft Cherry Vanilla		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Cherry Vanilla		

Black & Mild Apple		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Apple		
SE0015603: Black & Mild® Vinyl Wood Tip		
Prince Albert Soft Cherry Vanilla		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Cherry Vanilla		
yl		
Prince Albert Soft Cherry Vanilla		
Cello (polypropylene plastic wrap)		
1 Cigar		
126.9 mm		
9.62 mm		
Plastic		
Cherry Vanilla		

The predicate tobacco products are sheet wrapped unfiltered cigars manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 9, 2019, FDA received six SE Reports from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acceptance letter to the applicant on December 16, 2019.

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 Travelle Mason on December 16, 2019.

The 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 in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE reviews dated January 8, 2020, 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 reviews dated February 4, 2020 and April 17, 2020 conclude 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

A chemistry review was completed by Jiu Ai on February 3, 2020.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the 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:

SE0015598 and SE0015602

- Tobacco blend
 - o 2.2% decrease in cigar filler weight
 - o 2.0% decrease in target tobacco weight
 - 3.9% increase in (b) (4)
 - o 2.5% decrease in (a)
 - 3.8% decrease in (b) (4)
- Non-tobacco ingredients in cigar filler
 - o Removal of (b) (4) mg/cigar of (b) (4)
 - o Removal of (b)(4) mg/cigar of (b)(4)
 - o Removal of mg/cigar of (b) (4)
 - o 2.3% decrease in
 - o 18.9% decrease in
 - o 13.9% decrease in
 - o 7.6% decrease in (6)(4)
 - o 23.0% decrease in
 - o 2.2% decrease in
 - o 14.9% decrease in (b) (4)
 - o 8.2% decrease in (b) (4)
 - o 4.8% decrease in (b) (4)
 - o 23.2% decrease in (b) (4)
 - o 4.3% decrease in (b) (4)
 - o 72.6% decrease in (1)(4)
 - o 0.2% decrease in (6) (4)
- Ingredients in cigar wrapper
 - o 67% tobacco (b) (4)
 - o 9.2% decrease in wrapper weight
 - o 9.4% decrease in tobacco content
 - o 8.5% decrease in (b) (4)
 - o 9.0% decrease in
 - o 9.3% decrease in (b) (4)
 - 9.2% decrease in (b) (4)
 - o 9.7% decrease in (b) (4)
 - o Addition of mg/cigar of
 - Removal of (b) (4) mg/cigar of (b)
- · Ingredients in cigar binder
 - o 67% tobacco (b) (4) content
 - 11.2% decrease in binder weight

- 11.3% decrease in tobacco content
 11.1% decrease in 11.0% decrease
- Ingredients in seam adhesive
 - o 10.2% decrease in seam adhesive weight
 - 9.7% decrease in
- Ingredients in wood cigar tip (SE0015598)
 - Addition of (b) (4)
 Removal of (b) (4)
 Removal of (b) (4)
 Removal of (b) (4)
 Mg/cigar of (b) (4)
 Mg/cigar of (b) (4)
 Mg/cigar of (b) (4)
 Mg/cigar of (b) (4)
- Ingredients in plastic cigar tip (SE0015602)
 - o 1.0% decrease in
 - Addition of mg/cigar of (b)(4)

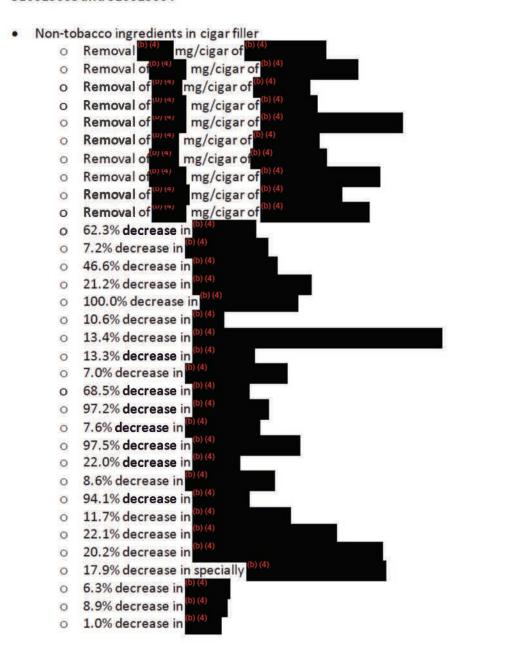
SE0015599 and SE0015601

- Non-tobacco ingredients in cigar filler
 - Removal of mg/cigar of Removal of mg/cigar of 0 Removal of (b) (4)
 Removal of (b) (4) mg/cigar of 0 mg/cigar of Removal of mg/cigar of Removal of mg/cigar of Removal of mg/cigar of 81.1% decrease in 76.2% decrease in 67.8% decrease in 0 21.2% decrease in 6.5% decrease in 0 10.6% decrease in 0 o 13.4% decrease in o 13.3% decrease in o 53.6% decrease in 68.5% decrease in o 87.1% decrease in 7.6% decrease in o 97.5% decrease in

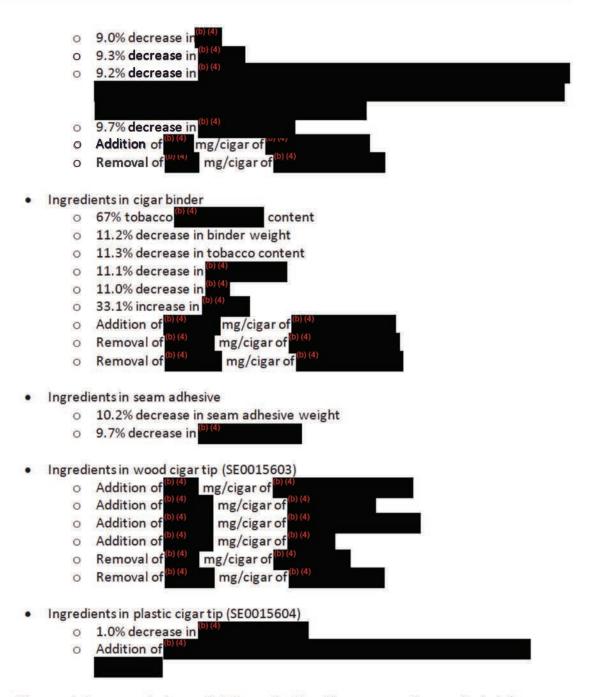
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20.4% decrease in
       88.6% decrease in
    0
       8.6% decrease in
    0
       59.7% decrease in
       12.8% decrease in
       22.1% decrease in
       18.8% decrease in
       17.9% decrease in (b) (4)
    0
       6.3% decrease in
       8.5% decrease in
       1.1% decrease in
Ingredients in cigar wrapper
    o 67% tobacco
                                  content
    o 9.2% decrease in wrapper weight
    o 9.4% decrease in tobacco content
    o 8.5% decrease in
       9.0% decrease in
       9.3% decrease in
       9.2% decrease in
    o 9.7% decrease in
       Addition of mg/cigar of
       Removal of
                       mg/cigar of
Ingredients in cigar binder
    o 67% tobacco
                                  content
       11.2% decrease in binder weight
    o 11.3% decrease in tobacco content
    o 11.1% decrease in
       11.0% decrease in
       33.1% increase in
    0
       Addition of
                           mg/cigar of
                          mg/cigar of
       Removal of
       Removal of
                            mg/cigar of
Ingredients in seam adhesive
       10.2% decrease in seam adhesive weight
       9.7% decrease in
Ingredients in wood cigar tip (SE0015599)
    o Addition of (b) (4) mg/cigar of
    o Addition of (b) (4)5 mg/cigar of
    o Addition of(b) (4) mg/cigar of
    o Addition of(b) (4) mg/cigar of
       Removal (b) (4) mg/cigar of
       Removal of(b) (4) mg/cigar of
```

- Ingredients in plastic cigar tip (SE0015601)
 - o 1.0% decrease in
 - O Addition of (b)(4) mg/cigar of (b)(4)

SE0015603 and SE0015604



- Ingredients in cigar wrapper
 - o 67% tobacco content
 - 9.2% decrease in wrapper weight
 - o 9.4% decrease in tobacco content
 - 0 8.5% decrease in (b) (4)



The new tobacco products are slightly smaller than the corresponding predicate tobacco products, with general decreases in tobacco and either decreases or removal of non-tobacco ingredients. Such changes are typically favorable because they reduce smoke constituents that have toxicological significance. The new tobacco products of SE0015598 and SE0015602 have increased in the cigar filler. An increase in can raise TSNA levels, however the analytically equivalent tobacco filler amounts of NNN and NNK between the new and corresponding predicate products in the tobacco filler demonstrate that this tobacco blend change does not cause concerns. (b)(4) replaces (b)(4) replaces (b)(4) (both preservatives) and (b)(4) is increased. Smoke chemistry is not anticipated to be affected by either of these changes because the (b)(4) quantity is less than (b)(4) of the tobacco rod weight of the cigar and the total amount of (b)(4)

mg/cigar lower in the new tobacco products compared to the corresponding predicate tobacco products. Finally, the new tobacco products use a corresponding predicate tobacco products use cigar tips of a non-combusted component, smoke chemistry is also not anticipated to be altered by this change. Smoke chemistry information was not provided. With the exception nicotine, on a unit of mass per gram of tobacco rod basis, arsenic, cadmium, NNK and NNN are analytically equivalent in the new tobacco products. Nicotine is increased 7-12% but does not cause concerns from a behavioral and clinical pharmacology perspective. As a result, the harmful and potentially harmful constituents (HPHC) data submitted for tobacco filler is sufficient and smoke data is not needed.

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

An engineering review was completed by Jimin P. Kim on January 23, 2020.

The 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:

- 6-8% decreases in tobacco filler mass (SE0015599, SE0015601, SE0015603, SE0015604)
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- Increases in tobacco cut size (CPI)

Decreases in tobacco mass, moisture in wrapper and binder, and increases in tobacco cut size, are all generally associated with a reduction in TNCO yields. The engineering review deferred evaluation of TNCO to chemistry.

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. MICROBIOLOGY

A microbiology review was completed by Wen S. Lin on January 28, 2020.

The microbiology review concludes that the new tobacco products have different characteristics related to product microbiology compared to the corresponding predicate

¹ CTP Memorandum: March 5, 2018, BCP Reviews of Characteristic Changes in SE Reports

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:

≤ 1% decrease in (a) (b) (c) (a) (all humectants)
 Removal of (b) (d) (all humectants)
 Replacement of (b) (d) (all humectants)
 Replacement of (b) (d) (all humectants)
 The seam adhesive (all humectants) (all humectants)
 10% decrease in (b) (d) (all humectants)

All new and corresponding predicate tobacco products differ in humectant and preservative content, which could potentially affect microbial stability of the products over the storage time of the products. The applicant did not provide stability data, but they provided moisture content (OV%), NNN and NNK content of the finished new and corresponding predicate tobacco products. The moisture content (< 16%) decrease in OV% (\leq 7%) and analytically equivalent NNN and NNK quantities demonstrate that the differences in humectants and preservatives in the new tobacco products are not a concern.

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.

4.4. TOXICOLOGY

A toxicology review was completed by Daniel Beury on January 30, 2020.

The 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 review identified the following differences:

- Decreases in non-tobacco ingredient additives
- Decreases in target weights for the binder, wrapper, and seam adhesive, which results in concomitant decreases of the respective ingredients
- Substitution of respectively
- Decreases in tobacco rod weight and the overall tobacco blends
- 3.9% increase in (SE0015598 and SE0015602)
- Change from a plastic tip to a wood tip (SE0015598, SE0015599, and SE0015603)
- Addition of artificial sweeteners (SE0015598, SE001599, and SE0015603) or just (SE0015601, SE0015602, and SE0015604) to the cigar tip

The change in ingredient levels do not present toxicological concerns because they are either reduced, do not affect HPHCs, or, in the cases of the artificial sweeteners, will be consumed in amounts that are less than those established by the Joint FAO/WHO Expert Committee on Food Additives Acceptable Daily Intake (JECFA ADI).

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 toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on January 23, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 12, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 12, 2020.

6. CONCLUSION AND RECOMMENDATION

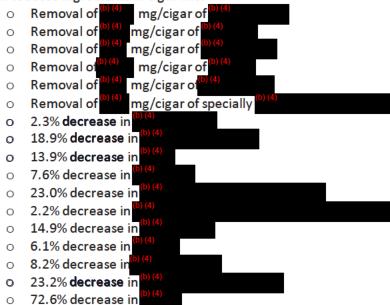
The following are the key differences in characteristics between the new and predicate tobacco products:

SE0015598 and SE0015602

Tobacco blend

- o 2.2% decrease in cigar filler weight
- o 2.0% decrease in target tobacco weight
- o 3.9% increase in (b) (4) tobacco
- o 2.5% decrease in tobacco
- 3.8% decrease in (1) (4)

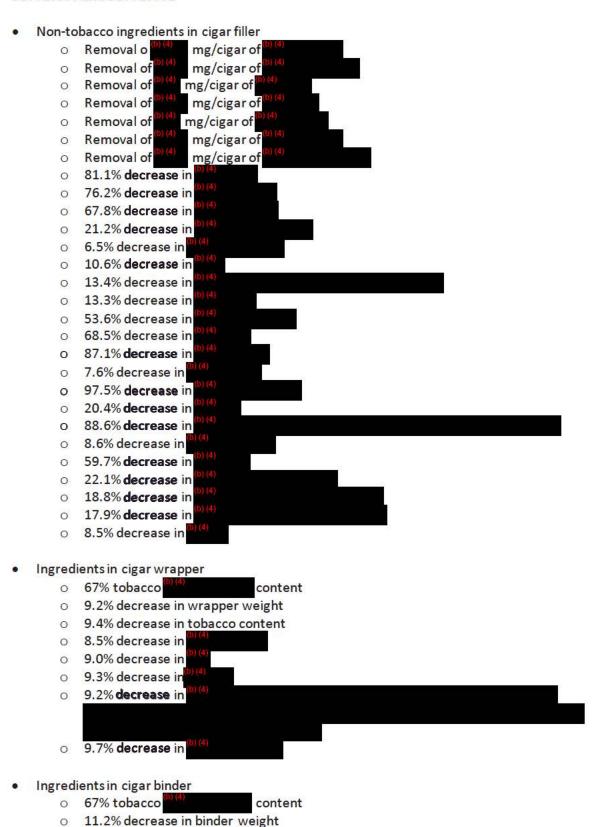
Non-tobacco ingredients in cigar filler



Ingredients in cigar wrapper 67% tobacco content 9.2% decrease in wrapper weight 9.4% decrease in tobacco content 8.5% decrease in 9.0% decrease in 9.3% decrease in 9.2% decrease in 9.7% decrease in Ingredients in cigar binder o 67% tobacco content 11.2% decrease in binder weight o 11.3% decrease in tobacco content o 11.1% decrease in o 11.0% decrease in 33.1% increase in Removal of mg/cigar of Ingredients in seam adhesive 9.7% decrease in Ingredients in wood cigar tip (SE0015598) Addition of mg/cigar of Addition of mg/cigar of Addition of mg/cigar of Addition of mg/cigar of mg/cigar of Removal of Removal of mg/cigar of Ingredients in plastic cigar tip (SE0015602) 1.0% decrease in Addition of (6) (4) mg/cigar of

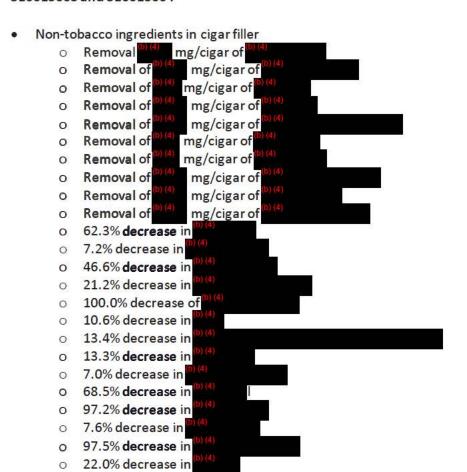
o 11.3% decrease in tobacco content

SE0015599 and SE0015601



- 11.1% decrease in (b) (4)
 11.0% decrease in (b) (4)
 33.1% increase in (b) (4)
 Removal of (b) (4)
 mg/cigar of (b) (4)
- Ingredients in seam adhesive
 - o 9.7% decrease in (b)(4)
- Ingredients in wood cigar tip (SE0015599)
 Addition of mg/cigar of mg/
 - Addition of (b) (4)
 Addition of (b) (4)
 Addition of (b) (4)
 Mg/cigar of (b) (4)
 Mg/cigar of (b) (4)
 - O Removal of (b) (4) mg/cigar of (b) (4)
 O Removal of (b) (4) mg/cigar of (b) (4)
- Ingredients in plastic cigar tip (SE0015601)
 - o 1.0% decrease in
 - Addition of mg/cigar of (b) (4)

SE0015603 and SE0015604



```
8.6% decrease in
     o 94.1% decrease in

 22.1% decrease in

     o 20.2% decrease in red
     o 17.9% decrease in (b) (4)
     o 6.3% decrease in
         8.9% decrease in
Ingredients in cigar wrapper
     o 67% tobacco
                                    content
     o 9.2% decrease in wrapper weight
     o 9.4% decrease in tobacco content

 8.5% decrease in

 9.0% decrease in

 9.3% decrease in

         9.2% decrease in
        9.7% decrease in
Ingredients in cigar binder
     o 67% tobacco
                                    content
     o 11.2% decrease in binder weight
     o 11.3% decrease in tobacco content
     o 11.1% decrease in
     o 11.0% decrease in
         33.1% increase in
         Removal of
                             mg/cigar of
 Ingredients in seam adhesive

 9.7% decrease in

 Ingredients in wood cigartip (SE0015603)

    Addition of

                        mg/cigar of

    Addition of

                            mg/cigar of

    Addition of

                            mg/cigar of

    Addition of

                            mg/cigar of
         Removal of
                         mg/cigar of
         Removal of
                            mg/cigar of
Ingredients in plastic cigar tip (SE0015604)
     o 1.0% decrease in
        Addition of
                          mg/cigar of
```

All SE Reports

- $\leq 1\%$ decrease in water, $\leq 20\%$ lower lower (all humectants)
- Removal of (b) (4) as a preservative in the tobacco filler
- Replacement of bid with with as a preservative in the wrapper and binder
- 10.2% decrease in (b)(4) in the seam adhesive
- 6-8% decreases in tobacco filler mass (SE0015599, SE0015601, SE0015603, SE0015604)
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- Increases in tobacco cut size (CPI)
- Addition of artificial sweeteners (SE0015601, SE0015602, and SE0015604) to the cigar tip of the new products.

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Decreases in tobacco and non-tobacco ingredient additives will not adversely affect smoke chemistry because less material is combusted. Similarly, the change to a cigar tip is not a concern since it is a non-combusted component. The differences in humectants, preservatives and tobacco blend (increase in tobacco) can affect microbial activity and related HPHCs like NNN and NNK. However, these HPHCs are analytically equivalent. The use of artificial sweeteners on the cigar tips is not a concern as exposure via dermal and oral routes are less than JECFA ADI established guidelines. 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 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 new tobacco products are currently in compliance with the FD&CAct. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SF 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 SE0015598, SE0015599, SE0015601, SE0015602, SE0015603, and SE0015604, as identified on the cover page of this review.