Technical Project Lead (TPL) Review: SE0015619, SE0015620, SE0015629 and SE0015630

SE0015619: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015620: Benson & Hedges 100's Deluxe Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	55 %
Characterizing Flavor	None
Additional Property	None
SE0015629: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0015630: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3

Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.08.28 16:25:56 -04'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering 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)

Digitally signed by Matthew R. Holman -S
Date: 2020.08.31 07:39:46 -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:

SE0015619: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015620: Benson & Hedges 100's Deluxe Box	
Product Name	Benson & Hedges 100's Deluxe Ultra Lights Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	55%
Characterizing Flavor	None
Additional Property	None
SE0015629: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2

SE0015630: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3

The predicate tobacco products are combusted, filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 20, 2019, FDA received four SE Reports from Altria Client Services (ALCS), on behalf of Philip Morris USA Inc (PMUSA). FDA issued an Acceptance letter to the applicant on December 27, 2019. FDA issued a Deficiency letter on February 21, 2020. FDA issued an Extension letter on April 29, 2020 with a response due date of October 1, 2020. On June 11, 2020, FDA received the response to the Deficiency letter (SE0016646).

Product Name	SE Report	Amendments
Chesterfield Menthol Box	SE0015619	SE0016646
Benson & Hedges 100's Deluxe Box	SE0015620	
Chesterfield Menthol Box	SE0015629	
Chesterfield Menthol Box	SE0015630	

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 Iqra Javaid on December 27, 2019. The review concludes 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 product in SE0015620is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated January 22, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product in SE0015620 is

grandfathered and, therefore an eligible predicate tobacco product.

The predicate tobacco products in SE0015619, SE0015629 and SE0015630 were determined to be substantially equivalent by FDA under SE0014891, SE0014906, SE0014816. Therefore, this product is an eligible predicate tobacco product.

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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated August 21, 2020, 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

A chemistry review was completed by Jiu Ai on February 12, 2020.

The final 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:

SE0015619, SE0015629 and SE15630

- Composition changes in cigarette paper
  - 13.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 2.6% increase in (b) (4)
  - 16.0% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of (b) (4)
  - 321% increase in (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)

SE0015620

- Composition changes in cigarette paper
  - 13.7% increase in (b) (4)
  - 3.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 13.8% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of

  - 614% increase in (b) (4)
  - Removal (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)

For SE0015619, SE0015620, SE0015629 and SE0015630, new tobacco products have differences in the cigarette paper and tipping adhesive compared to the corresponding predicate tobacco products. The target weight of cigarette paper of the new tobacco products increased 3.6-4.2%, with 13-14% increase in (b) (4) 100% increase in (b) (4) , 2.6-3.2% increase in (b) (4) (calculated from the contents of (b) (4) and (b) (4) (b) (4)) and 14-16% decrease in (b) (4) . For Fire Standards Compliant (FSC) bands, the new tobacco products have 321-614% increase in (b) (4) , added (b) (4) to replace (b) (4) and addition of (b) (4) . The tipping adhesive of the new tobacco products has an added (b) (4) mg/cigarette or less (b) (4) (b) (4) and is not a chemistry concern. However, the change of cigarette paper and FSC band in the new tobacco products may alter the cigarette smoke chemistry and may cause the new tobacco products to raise different questions of public health. The reported tar, nicotine, and carbon monoxide (TNCO), harmful and potentially harmful constituents (HPHC)s and puff counts of the new tobacco products are equivalent to those of the corresponding predicate tobacco products with one exception. The formaldehyde yield from the new tobacco product in SE0015619 is higher than and not analytically equivalent to that of the corresponding predicate tobacco product under the Health Canadian Intense (HCI) smoking regimen. Since the tobacco products in SE0015629 and SE0015630 are almost identical to those in SE0015619, the higher formaldehyde yield may also occur in the new tobacco products in SE0015629 and SE0015630. This issue is deferred to toxicology review. For SE0015620, the reported TNCO, HPHC and puff counts are analytically equivalent between the new and predicate tobacco products and do not cause the new tobacco product to raise different questions of public health.

All the predicate tobacco products, except SE0015620, of this review are previously found SE products (SE0014886, SE0014279, SE0014891, SE0004306, SE0004305, SE0014906, SE0014816, SE0014888 and SE0014890) and were compared to the corresponding grandfathered tobacco products (GF1200272, GF1200100 and GF1200077). The cigarette components evaluated in this review are identical between the predicate and corresponding grandfathered tobacco products. The only difference between the three new tobacco products in SE0015619, SE0015629 and SE0015630 is the tipping papers. Although the applicant does not provide the information of the ventilation perforation method for tipping papers, for all new, predicate, and grandfathered tobacco products, the filter ventilation is 0% for SE0015619, SE0015629 and SE0015630. For ventilation less than 20%, the perforation method is not expected to affect the smoke yields and therefore the lack of information regarding perforation method is not a concern. In addition, the cigarette components with ingredient differences between the predicate and corresponding grandfathered tobacco products do not affect the smoke chemistry as determined by the substantial equivalence (SE) reviews of the predicate tobacco products in SE0015619, SE0015629, SE0015630. Therefore, the smoke yields of TNCO and HPHCs from the grandfathered tobacco products are expected to be equivalent to those of the predicate tobacco products, which are equivalent to those of the new tobacco products with one exception as evaluated in this review. The non-equivalent formaldehyde yields between the new and predicate tobacco products is deferred to

toxicology review for SE0015619 (which may also include SE0015629 and SE0015630). The TNCO and tobacco specific nitrosamines (TSNA) yields of the current predicate tobacco product are lower than the HPHC yields of the corresponding grandfathered tobacco products and therefore the predicate tobacco products do not raise different questions of public health. Therefore, due to the similarities between the new and corresponding predicate tobacco products, the differences in tobacco blend, cigarette papers, FSC bands, cigarette seam adhesive, monogram ink, tipping adhesive, tipping ink and ink extender between the new and corresponding grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health in SE0015620.

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 reviews was completed by Pritesh Darji on February 12, 2020.

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 applicant submitted certification statements for each SE Report, noting many of the design parameters are the same between the new and predicate tobacco products. For SE0015619, SE0015620, SE0015629, and SE0015630, the certification statements did not cover parameters such as base paper basis weight, base paper porosity, band porosity, band width and band space, so the differences in these parameters between the new and predicate tobacco products were evaluated. The differences are not likely to cause measurable differences in mainstream smoke yield, and, therefore, they do not cause the new tobacco products to raise different questions of public health. None of these differences resulted in deferrals 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 and engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Prabha Kc on February 11, 2020 and July 24, 2020.

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 review identified the following differences:

<u>Cigarette paper ingredients</u>

Ingredients added:

- SE0015619, SE0015629, SE0015630: (b) (4) mg/cig); (b) (4) (b) (4) mg/cig)
- SE0015620: (b) (4) mg/cig)

Ingredients increased:

- SE0015619, SE0015629, SE0015630: (b) (4) mg/cig, ↑100%); (b) (4) (b) (4) mg/cig; ↑2.8%)

Harmful and Potentially Harmful Constituents (HPHCs) in the Mainstream Smoke (MSS)

HPHCs significantly increased and analytically non-equivalent:

- SE0015619, SE0015629, and SE0015630: formaldehyde (↑20%; Canadian Intense (CI) smoking regimen)

Propylene glycol was newly added to the cigarette paper in the new tobacco products of SE0015619, SE0015620, SE0015629, and SE0015630. Potential pyrolysis products from (b) (4) of toxicological concern are propylene oxide and (b) (4). The applicant cited reference articles to state that the majority of (b) (4) is recovered following pyrolysis, and as such, HPHC generation from (b) (4) is minimal. Additionally, the applicant stated that the TNCO and acetaldehyde are comparable between the new and corresponding predicate tobacco products, and as such, addition of (b) (4) to cigarette paper does not cause a new product to raise different questions of public health. However, the applicant did not address the toxicological concerns of pyrolysis products of (b) (4) The toxicological concerns that arise from a potential pyrolysis product of propylene oxide and (b) (4) cannot be offset by the HPHCs that are considered analytically equivalent between the new and predicate tobacco products. Considering 0.1% of (b) (4) undergoes pyrolysis as per (b) (4) (b) (4) the reviewer assessed the estimated daily exposures of propylene oxide and propanal from pyrolysis of (b) (4) in the new tobacco products. The daily intake amounts of propylene oxide and (b) (4) are 30—38 and 8—10 -folds, respectively, lower (non-cancer toxicity) than the estimated intake of propylene oxide and (b) (4) per day based on the U.S. EPA chronic inhalation reference concentration (RfC) values, respectively. Thus, there are no toxicological concerns from the added (b) (4) in the new tobacco products.

The formaldehyde yield was significantly increased (20%) in the new tobacco products compared to the corresponding predicate tobacco products in SE0015619, SE0015629, and SE0015630 under the CI smoking regimen. The applicant contended that the increase in formaldehyde yield only under the CI smoking regimen is related to analytical variability given that the new and the corresponding predicate products have identical cigarette design parameters. Therefore, considering i) other volatile organic compounds such as acrolein, acetaldehyde, toluene, and benzene were analytically equivalent as determined by Chemistry between the new and the corresponding predicate tobacco products under both the International Organization for Standardization (ISO) and CI smoking regimens; ii) the applicant, as determined by Chemistry, has provided sufficient testing information such as analytical methods, testing conditions, number of replicates, raw data, standard results,

accreditation of the laboratory, and dates of manufacture and testing,; iii) the new and the corresponding predicate products have identical cigarette design parameters (i.e., filler mass, ventilation, cigarette length and circumference); iv) the formaldehyde yields (ISO and CI smoking regimens) data using the matched pair protocol submitted in this amendment to justify potential analytical variability in formaldehyde yield measurements is in concordance to the CTP memorandum (2017); v) the formaldehyde yields in the new tobacco product of SE0015630, provided in the amendment using the matched pair protocol, were analytically equivalent to the predicate tobacco product under both the ISO and CI smoking regimens, based on the two-one sided t-test (TOST) equivalency analysis performed by the Chemistry reviewer, the addition of (b) (4), and an increase in (b) (4) and (b) (4) and the potential increase in formaldehyde yield do not cause the new tobacco products in SE0015619, SE0015629, and SE0015630 to raise different questions of public health from a toxicology perspective.

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

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on July 23, 2020. The FONSI was supported by an environmental assessment prepared by FDA on July 23, 2020.

6. CONCLUSION AND RECOMMENDATION

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

SE0015619, SE0015629 and SE15630

- Composition changes in cigarette paper
  - 13.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 2.6% increase in (b) (4)
  - 16.0% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of (b) (4)
  - 321% increase in (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)
- Formaldehyde analytically non-equivalent (↑20%; CI smoking regimen)

SE0015620

- Composition changes in cigarette paper
  - 13.7% increase in (b) (4)
  - 3.2% increase in (b) (4)

    - 100% increase in (b) (4)
    - 13.8% decrease in (b) (4)
- Composition changes in cigarette paper bands
    - Addition of (b) (4)
    - Addition of (b) (4)
    - 614% increase in (b) (4)
    - Removal (b) (4)
- Composition changes in tipping adhesive
    - Addition of (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For SE0015619, SE0015620, SE0015629 and SE0015630, the new tobacco products have differences in the cigarette paper and tipping adhesive compared to the corresponding predicate tobacco products. The added (b) (4) to the tipping adhesive of the new tobacco products is not a chemistry concern because the tipping adhesive is not combusted during smoking and thus is not expected to have an impact on smoke chemistry composition. The target weight of cigarette paper of the new tobacco products increased, with an increase in (b) (4), increase in (b) (4), increase in (b) (4) (b) (4) and decrease in (b) (4). For Fire Standards Compliant (FSC) bands, the new tobacco products have an increase in (b) (4), added (b) (4) to replace (b) (4), and addition of (b) (4). Potential pyrolysis products from (b) (4) of toxicological concern are propylene oxide and propanal. The applicant cited reference articles to state that the majority of (b) (4) is recovered following pyrolysis, and as such, HPHC generation from (b) (4) is minimal. Additionally, the applicant stated that the TNCO and acetaldehyde are comparable between the new and corresponding predicate tobacco products, and as such, addition of (b) (4) to cigarette paper does not cause a new product to raise different questions of public health. However, the toxicological concerns that arise from a potential pyrolysis product of , propylene oxide and propanal, cannot be offset by the HPHCs that are considered analytically equivalent between the new and predicate tobacco products. Nevertheless, considering 0.1% of (b) (4) undergoes pyrolysis as per (b) (4) (b) (4)), the toxicology reviewer assessed the estimated daily exposures of propylene oxide and (b) (4) from pyrolysis of (b) (4) in the new tobacco products. The daily intake amounts of propylene oxide and propanal are 30—38 and 8—10 -folds, respectively, lower (non-cancer toxicity) than the estimated intake of propylene oxide and (b) (4) per day based on the U.S. EPA chronic inhalation reference concentration (RfC) values, respectively. Therefore, there are no toxicological concerns from the added (b) (4) in the new tobacco products.

The reported tar, nicotine, and carbon monoxide (TNCO), harmful and potentially harmful constituents (HPHC)s and puff counts of the new tobacco products are equivalent to those of the corresponding predicate tobacco products with one exception: formaldehyde. The formaldehyde yield was significantly increased (20%) in the new tobacco products compared to the corresponding predicate tobacco products in SE0015619, SE0015629, and SE0015630 under the CI smoking regimen. The applicant contended that the increase in formaldehyde yield under the CI smoking regimen is related to analytical variability, given that the new and the corresponding predicate products have identical cigarette design parameters. Therefore, considering i) other volatile organic compounds such as acrolein, acetaldehyde, toluene, and benzene were analytically equivalent as determined by Chemistry between the new and the corresponding predicate tobacco products under both the ISO and CI smoking regimens; ii) the applicant, as determined by Chemistry, has

provided sufficient testing information such as analytical methods, testing conditions, number of replicates, raw data, standard results, accreditation of the laboratory, and dates of manufacture and testing,; iii) the new and the corresponding predicate products have identical cigarette design parameters (i.e., filler mass, ventilation, cigarette length and circumference); iv) the formaldehyde yields (ISO and CI smoking regimens) data using the matched pair protocol submitted in this amendment to justify potential analytical variability in formaldehyde yield measurements is in concordance to the CTP memorandum (2017); v) the formaldehyde yields in the new tobacco product of SE0015630, provided in the amendment using the matched pair protocol, were analytically equivalent to the predicate tobacco product under both the ISO and CI smoking regimens, based on the TOST equivalency analysis performed by the Chemistry reviewer, the addition of (b) (4), and an increase in (b) (4) and (b) (4), and the potential increase in formaldehyde yield do not cause the new tobacco products in SE0015619, SE0015629, and SE0015630 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 product in SE0015620 meets statutory requirements because it was determined that it is a grandfathered tobacco product (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 SE0015619, SE0015629 and SE0015630 were previously determined to be substantially equivalent by FDA under SE0014891, SE0014906 and SE0014816.

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 as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco products in SE0015619, SE0015629 and SE0015630 were previously determined to be substantially equivalent by FDA under SE0014891, SE0014906 and SE0014816, respectively. Comparison of the new tobacco products to the grandfathered tobacco product (Basic Menthol Box in SE0014891, SE0014906 and SE0014816) reveals that the new tobacco products have the following differences in characteristics from Basic Menthol Box, the grandfathered tobacco product:

SE0015619 (vs. GF1200077)

- Composition changes in tipping paper
  - Addition of (b) (4)
  - 1627% increase in (b) (4)
  - 1.8% decrease of (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping ink
  - Addition of (b) (4)
  - 305% increase in (b) (4)
  - Removal of (b) (4)
  - 41.3% decrease of (b) (4)
  - 25.8% decrease of
  - Removal of (b) (4)
  - Addition of (b) (4)

- Composition changes in tipping ink extender
  - 25.4% decrease in (b) (4)
  - Changes of ingredients with less than (b) (4) mg/cigarette
- Composition changes in cigarette paper
  - 13.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 2.6% increase in (b) (4)
  - 16.0% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of (b) (4)
  - 321% increase in (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)
- Formaldehyde analytically non-equivalent (↑20%; CI smoking regimen)

SE0015629 (vs. GF1200077)

- Composition changes in tipping paper
  - Addition of (b) (4)
  - 1627% increase in (b) (4)
  - 1.8% decrease of (b) (4)
  - 34.2% decrease of (b) (4)
- Composition changes in tipping ink
  - Addition of (b) (4)
  - 305% increase in (b) (4)
  - Removal of (b) (4)
  - 41.3% decrease of (b) (4)
  - 25.8% decrease of
  - 20.0% decrease of
- Composition changes in tipping ink extender
  - 25.4% decrease of (b) (4)
  - Changes of ingredients with less than (b) (4) mg/cigarette
- Composition changes in cigarette paper
  - 13.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 2.6% increase in (b) (4)
  - 16.0% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of (b) (4)
  - 321% increase in (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)
- Formaldehyde analytically non-equivalent (↑20%; CI smoking regimen)

SE0015630 (vs. GF1200077)

- Composition changes in tipping paper
  - Addition of (b) (4) and (b) (4)
  - 3.7% increase in (b) (4)
  - Removal of (b) (4)
  - 1.9% decrease of (b) (4)
- Composition changes in tipping ink
  - Addition of (b) (4)
  - 257% increase in (b) (4)
  - Removal of (b) (4) and (b) (4)
  - 46.3% decrease of (b) (4)
  - 27.0% decrease of
  - 32.5% decrease of
- Composition changes in tipping ink extender
  - 29.2% decrease of (b) (4)
  - Changes of ingredients with less than (b) (4) mg/cigarette
- Composition changes in cigarette paper
  - 13.2% increase in (b) (4)
  - 100% increase in (b) (4)
  - 2.6% increase in (b) (4)
  - 16.0% decrease in (b) (4)
- Composition changes in cigarette paper bands
  - Addition of (b) (4)
  - Addition of (b) (4)
  - 321% increase in (b) (4)
  - Removal of (b) (4)
- Composition changes in tipping adhesive
  - Addition of (b) (4)
- Formaldehyde analytically non-equivalent (↑20%; CI smoking regimen)

The differences in characteristics listed above, other than the ingredient differences in the tipping paper, tipping ink, and tipping extenders, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014891, SE0014906 and SE0014816. Therefore, these differences do not cause the new tobacco products in SE0015619, SE0015629 and SE0015630 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in the cigarette paper, cigarette paper bands, and tipping adhesive between the new tobacco products in SE0015619, SE0015629 and SE0015630 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015619, SE0015629 and SE0015630 to the predicate of grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

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 are such that the new tobacco products do not 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 SE0015619, SE0015620, SE0015629 and SE0015630, as identified on the cover page of this review.