Technical Project Lead (TPL) Review: SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634

SE0015617: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 millimeters (mm)
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015618: Marlboro Black Special Blend Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None
SE0015621: Marlboro Eighty-Threes Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None
SE0015622: Marlboro Soft Pack	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None

SE0015633: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015634: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 3
Common 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: 2020.03.18 11:04:39 -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: 2020.03.18 11:23:51 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015617: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015618: Marlboro Black Special Blend Box	
Product Name	Marlboro Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None
SE0015621: Marlboro Eighty-Threes Box	
Product Name	Marlboro Eighty-Threes Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None

SE0015622: Marlboro Soft Pack	
Product Name	Marlboro Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	None
SE0015633: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015634: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
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 six SE Reports from Altria Client Services LLC (ALCS), on behalf of Philip Morris USA Inc. On December 27, 2019, FDA issued an Acceptance letter.

On January 8, 2020, FDA received an amendment (SE0015643) from ALCS to correct a typographical error of the new tobacco product name for SE0015617, SE0015633, and SE0015634.

Product Name	SE Report	Amendments
Marlboro Black Special Blend 100's Box	SE0015617	SE0015643
Marlboro Black Special Blend Box	SE0015618	None
Marlboro Eighty-Threes Box	SE0015621	None
Marlboro Soft Pack	SE0015622	None
Marlboro Black Special Blend 100's Box	SE0015633	SE0015643
Marlboro Black Special Blend 100's Box	SE0015634	SE0015643

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 Iqra Javaid on December 27, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634 were determined to be substantially equivalent by FDA under SE0014886, SE0014279, SE0004306, SE0004305, SE0014888, and SE0014890, respectively. Therefore, the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) 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 section910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated February 27, 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. C HEMISTRY

A chemistry review was completed by Jiu Ai on February 12, 2020 and an addendum to this review was completed on March 10, 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:

SE0015617, SE0015618, SE0015633 and SE0015634

- Composition changes in cigarette seam adhesive
  - 47.4% decrease in [redacted]
  - Addition of [redacted]
  - Removal of [redacted]
  - Addition of a [redacted]
  - 367% increase in [redacted]
- Composition changes in monogram ink
  - 7-17% decrease in all ingredients
  - Removal of [redacted]
- Composition changes in tipping adhesive
  - Addition of [redacted]

SE0015621 and SE0015622

- Composition changes in cigarette seam adhesive
  - 47.4% decrease in [redacted]
  - Addition of [redacted]
  - Removal of [redacted]
  - Addition of a [redacted]
  - 367% increase in [redacted]

In SE0015617, SE0015618, SE0015633, and SE0015634, the new tobacco products have differences in the cigarette seam adhesive, monogram ink and tipping adhesive compared to the corresponding predicate tobacco products. In SE0015621 and SE0015622, the new tobacco products have differences in the cigarette seam adhesive only, compared to the corresponding predicate tobacco products. The cigarette seam adhesive of the new tobacco products reported in SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634 has a 47% decrease in [redacted] and 367% increase in [redacted] compared to the corresponding predicate tobacco products. A decrease of [redacted] and increase of [redacted] are not a chemistry concern as these changes are not expected to have a measurable impact on mainstream smoke (MSS) harmful and potentially harmful constituent (HPHC) yields. Small quantities of [redacted] are added and [redacted] is removed from the cigarette seam adhesive. The quantities of added and removed ingredients are less than [redacted] mg (< 0.1% of cigarette weight). Addition of small quantities of [redacted] (< 0.1% of cigarette weight) are not expected to alter the smoke chemistry. Therefore, these changes in cigarette seam adhesive do not cause the new tobacco products to raise different questions of public health. In SE0015617, SE0015618, SE0015633 and SE0015634, the differences in the target quantities of monogram ink ingredients are less than [redacted] mg/cigarette. Such small quantities of ingredient change are not expected to affect the smoke chemistry. In addition, in SE0015617, SE0015618, SE0015633, and SE0015634, [redacted] was removed from the monogram ink in the new tobacco products and, as such, there is no chemistry concern. The applicant provided smoke yield data for SE0015617 and SE0015618 showing analytically equivalent yields of tar, nicotine, and carbon monoxide (TNCO) and other HPHCs between the new and corresponding predicate tobacco products.

The change in tipping adhesive is adding (b) (4) mg/cigarette or less (b) (4) in the tipping adhesive of the new tobacco products. This change does not affect the cigarette smoke chemistry. Therefore, the modifications to the new tobacco products in these six SE Reports do not 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 chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Pritesh Darji on February 12, 2020.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from an engineering 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 related to product engineering.

4.3. TOXICOLOGY

A toxicology review was completed by Prabha Kc on February 11, 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:

Cigarette seam adhesive ingredients added:

- SE0015617, SE0015633, SE0015634: (b) (4) mg/cig); (b) (4) mg/cig); (b) (4)
- SE0015618, SE0015621, SE0015622: (b) (4) mg/cig); (b) (4) mg/cig); (b) (4)

Monogram ink ingredients removed:

- SE0015617, SE0015618, SE0015633, and SE0015634: (b) (4) mg/cig)

Tipping adhesive ingredients added:

- SE0015617, SE0015618, SE0015633, and SE0015634: (b) (4) mg/cig)

For all SE Reports, the applicant provided a certification stating that each new tobacco product is identical to its corresponding predicate tobacco product with the exception of minor differences in cigarette seam adhesive, monogram ink, and tipping adhesive (SE0015617, SE0015618, SE0015633, SE0015634), or cigarette seam adhesive only (SE0015621, SE0015622).

To support that the newly added (b) (4) in the cigarette seam adhesive does not impact HPHC yields in the new tobacco products in SE0015621 and SE0015622, the applicant manufactured Test Cigarettes A and B. Both of the test cigarettes used the same lot of tobacco cut filler with identical components, tobacco ingredients, and structural materials. Test Cigarette A contained the cigarette seam adhesive inclusive of the (b) (4) used in the new tobacco products in SE0015621 and SE0015622. Test Cigarette B contained all the ingredients in the cigarette seam adhesive except the (b) (4) used in the new tobacco products in SE0015621 and SE0015622.

Additionally, to support that the newly added ingredients in the cigarette seam adhesives do not impact constituent levels in smoke in the new tobacco products in SE0015621 and SE0015622, the applicant manufactured Test Cigarettes 1 and 2. Both of the test cigarettes used the same lot of tobacco cut filler with identical components, identical tobacco ingredients, and identical structural materials. Test Cigarette 1 contained the identical cigarette seam adhesives used in the new tobacco products in SE0015621 and SE0015622. Test Cigarette 2 contained the identical cigarette seam adhesives used in the corresponding predicate tobacco products in SE0015621 and SE0015622.

Although neither set of test cigarettes is identical to any of the new or predicate tobacco products, the HPHC yields reported in these test cigarettes could be used to inform whether the added ingredients in the cigarette seam adhesive can cause the new tobacco products to raise different questions of public health from a toxicological perspective.

The cigarette seam adhesive ingredients (b) (4) were newly added to the new tobacco products in all SE Reports. In SE0015617, SE0015618, SE0015633, and SE0015634, the MSS HPHC yields were analytically equivalent between the new and corresponding predicate tobacco products. In SE0015621 and SE0015622, as described above, the applicant provided the HPHC yields in test cigarettes manufactured with identical tobacco, tobacco ingredients, and structural material inclusive of the cigarette seam adhesive used in the respective new and predicate tobacco products under both the International Organization for Standardization (ISO) and Canadian Intense (CI) smoking regimens. These HPHC yields were comparable between the test cigarettes manufactured using the same tobacco filler with identical components, tobacco ingredients, and structural materials, inclusive of the respective cigarette seam adhesive used in the new and predicate tobacco products, under both the ISO and CI smoking regimens. The newly added ingredients in the cigarette seam adhesive are unlikely to cause the new tobacco products to raise different questions of public health due to the following: small quantities of (b) (4) ingredients were added; small increases (0.0004%) in the total weight of the (b) (4) in the overall amount of the cigarette; analytically equivalent HPHC yields between the new and corresponding predicate tobacco products in SE0015617, SE0015618, SE0015633, and SE0015634 or comparable HPHC yields in the test cigarettes manufactured using the same tobacco filler with identical components, tobacco ingredients, and structural materials, inclusive of the respective cigarette seam adhesive used in the new and predicate tobacco products in SE0015621 and SE0015622, under both the ISO and CI smoking regimens.

In SE0015617, SE0015618, SE0015633, and SE0015634, (b) (4) was removed from the monogram ink in the new tobacco products and, as such, there is no toxicological concern.

In SE0015617, SE0015618, SE0015633, and SE0015634, (b) (4) was newly added in the tipping adhesive of the new tobacco products. (b) (4) in the tipping adhesive is not expected to be burned, volatilized, or to be a potential source of thermal degradation or pyrolysis resulting in the release of HPHCs for inhalation exposure. Therefore, the added (b) (4) does not cause the new tobacco products to raise different questions of public health from a toxicological perspective.

In SE0015617, SE0015618, SE0015633, and SE0015634, MSS TNCO as well as HPHC yields [acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), N-Nitrosonornicotine (NNN), toluene] provided by the applicant were analytically equivalent between the new and corresponding predicate tobacco products under both the ISO and CI smoking regimens. In SE0015621 and SE0015622, the measured HPHCs (acetaldehyde, acrolein, acrylonitrile, 1-aminonaphthalene, 2-aminonaphthalene, 4-aminobiphenyl, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, CO, crotonaldehyde, formaldehyde, isoprene, nicotine, NNK, NNN, toluene) and tar yields were comparable in the test cigarettes that were manufactured using the same tobacco filler with identical components, tobacco ingredients, and structural materials, inclusive of the respective cigarette seam adhesive used in the new and predicate tobacco products, under both the ISO and CI smoking regimens. Therefore, the HPHC yield changes in SE0015621 and SE0015622 do not cause the new tobacco products to raise different questions of public health from a toxicological 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

An environmental review was completed by Thomas Creaven on January 29, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 5, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 4, 2020.

6. CONCLUSION AND RECOMMENDATION

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

SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634

- Composition changes in cigarette seam adhesive
  - Added [redacted] mg/cig); [redacted] mg/cig); [redacted]

SE0015617, SE0015618, SE0015633, and SE0015634

- Composition changes in monogram ink
  - Removed [redacted] mg/cig)
- Composition changes in tipping adhesive
  - Added [redacted] mg/cig)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. In all SE Reports, the applicant provided a certification stating that each new tobacco product is identical to its corresponding predicate tobacco product with the exception of minor differences in cigarette seam adhesive, monogram ink, and tipping adhesive (SE0015617, SE0015618, SE0015633, SE0015634), or cigarette seam adhesive (SE0015621, SE0015622). As described in sections 4.1 and 4.3, the quantities of ingredients added or removed is very small and is not expected to alter smoke chemistry. Therefore, changes in cigarette seam adhesive do not cause the new tobacco products to raise different questions of public health.

In SE0015617, SE0015618, SE0015633, and SE0015634, [redacted] was removed from the monogram ink and the target quantities of the monogram ink ingredients are all less than [redacted] mg/cigarette. Such small quantities of ingredient change are not expected to affect the smoke chemistry and therefore do not cause the new tobacco products to raise different questions of public health.

In SE0015617, SE0015618, SE0015633, and SE0015634, [redacted] was newly added in the tipping adhesive of the new tobacco products. [redacted] in the tipping adhesive is not expected to be burned, volatilized, or to be a potential source of thermal degradation or pyrolysis resulting in the release of HPHCs for inhalation exposure. Therefore, the added [redacted] does not cause the new tobacco products to raise different questions of public health.

In SE0015617, SE0015618, SE0015633, and SE0015634, MSS TNCO as well as HPHC yields were analytically equivalent between the new and corresponding predicate tobacco products under both the ISO and CI smoking regimens. Therefore, the HPHC yield changes in SE0015617, SE0015618, SE0015633, and SE0015634 do not to cause the new tobacco products to raise different questions of public health. In SE0015621 and SE0015622, the measured HPHCs (acetaldehyde, acrolein, acrylonitrile, 1-aminonaphthalene, 2-aminonaphthalene, 4-aminobiphenyl, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, CO, crotonaldehyde, formaldehyde, isoprene, nicotine, NNK, NNN, toluene) and tar yields were comparable in the test cigarettes that were manufactured using the same tobacco filler with identical components, tobacco ingredients, and structural materials, inclusive of the respective cigarette seam adhesive used in the new and predicate tobacco products, under both the ISO and CI smoking regimens (see section 4.3 for more information regarding the test cigarettes). Therefore, potential HPHC yield differences that may result due to the changes in the cigarette seam adhesive ingredients in the new tobacco products in SE0015621 and SE0015622 when compared to the corresponding predicate tobacco products do not to cause the new tobacco products to raise different questions of public health.

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

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 SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634 were previously determined to be substantially equivalent by FDA under SE0014886, SE0014279, SE0004306, SE0004305, SE0014888, and SE0014890, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Marlboro 100's Soft Pack in SE0014886 [GF1200272], Marlboro Soft Pack in SE0014279 [GF1200100], Marlboro Soft Pack in SE0004306 [GF1200100], Marlboro Soft Pack in SE0004305 [GF1200100], Marlboro 100's Soft Pack in SE0014888 [GF1200272], Marlboro 100's Soft Pack in SE0014890 [GF1200272]) reveals that the new tobacco products have the following differences in characteristics from the grandfathered tobacco products:

SE0015617 (vs. GF1200272)

- Composition changes in tipping paper
- Composition changes in tipping ink
- Composition changes in tipping ink extender
- Composition changes in cigarette seam adhesive
- Composition changes in monogram ink
- Composition changes in tipping adhesive

SE0015618 (vs. GF1200100)

- Composition changes in tipping ink
- Composition changes in tipping ink extender
- Composition changes in cigarette seam adhesive
- Composition changes in monogram ink
- Composition changes in tipping adhesive

SE0015621 and SE0015622 (vs. GF1200100)

- Tobacco blend changes
  - 34.6% increase in (b)(4) [redacted]
  - 1.2-7.5% decrease of all other tobacco types
- Composition changes in cigarette paper
- Composition changes in base tipping paper
- Composition changes in tipping adhesives
- Composition changes of tipping ink
- Composition changes in cigarette seam adhesive

SE0015633 (vs. GF1200272)

- Composition changes in tipping paper
- Composition changes in tipping ink

- Composition changes in tipping ink extenders
- Composition changes in cigarette seam adhesive
- Composition changes in monogram ink
- Composition changes in tipping adhesive

SE0015634 (vs. GF1200272)

- Composition changes in tipping paper
- Composition changes in tipping ink
- Composition changes in tipping ink extender
- Composition changes in cigarette seam adhesive
- Composition changes in monogram ink
- Composition changes in tipping adhesive

The differences in characteristics between the new and grandfathered tobacco products listed above for SE0015617 (vs. GF1200272), SE0015633 (vs. GF1200272), and SE0015634 (vs. GF1200272) are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014886, SE0014888, and SE0014890. Therefore, these differences do not cause the new tobacco products in SE0015617, SE0015633, and SE0015634 to raise different questions of public health. Additionally, for the same reasons as discussed above, composition differences in cigarette seam adhesive, monogram ink, and tipping adhesive between the new tobacco products in SE0015617, SE0015633, and SE0015634, 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 SE0015617, SE0015633 and SE0015634 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

The differences in characteristics between the new and grandfathered tobacco products listed above for SE0015618 (vs. GF1200100) are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014279. Therefore, these differences do not cause the new tobacco product in SE0015618 to raise different questions of public health. Additionally, for the same reasons as discussed above, composition differences in cigarette seam adhesive, monogram ink, and tipping adhesive between the new tobacco product in SE0015618, 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 SE0015618 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The differences in characteristics between the new and grandfathered tobacco products listed above for SE0015621 and SE0015622 (vs. GF1200100) (tobacco blend changes, composition changes in cigarette paper and base tipping paper) are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0004306 and SE0004305. Therefore, these differences do not cause the new tobacco products in SE0015621 and SE0015622 to raise different questions of public health. Additionally, for the same reasons as discussed above, composition differences in cigarette seam adhesive between the new tobacco products in SE0015621 and SE0015622 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Furthermore, the TNCO and tobacco specific nitrosamine (TSNA) yields of the predicate tobacco products in SE0015621 and SE0015622 are lower than or

analytically equivalent to the HPHC yields of the corresponding grandfathered tobacco products. Therefore, despite any of the differences between the new and grandfathered tobacco products noted above, the differences in HPHCs when comparing the new tobacco products to the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, when comparing the new tobacco products in SE0015621 and SE0015622 to the predicate or 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 SE0015617, SE0015618, SE0015621, SE0015622, SE0015633, and SE0015634 as identified on the cover page of this review.