FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015260-SE0015263

SE0015260: Marlboro Gold Pack 100's Soft Pack	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None
SE0015261: Marlboro Silver Pack Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	46%
Characterizing Flavor	None
SE0015262: Marlboro Silver Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	50%
Characterizing Flavor	None
SE0015263: Marlboro Gold Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2019.09.05 09:41:58 -04'00'

For CDR Samantha Spindel, USPHS
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: 2019.09.05 10:05:26 -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:

SE0015260: Marlboro Gold Pack 100's Soft Pack	
Product Name	**Marlboro Gold Pack 100's Box**
Package Type	Box
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0015261: Marlboro Silver Pack Box	
Product Name	**Marlboro Silver Pack Box**
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	46%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0015262: Marlboro Silver Pack 100's Box	
Product Name	**Marlboro Silver Pack 100's Box**
Package Type	Box
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	50%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0015263: Marlboro Gold Pack 100's Box	
Product Name	**Marlboro Gold Pack 100's Box**
Package Type	Box
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 7, 2019, FDA received four SE Reports (SE0015260-SE0015263) from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA issued an Acknowledgment letter to the applicant on June 14, 2019. No amendments were received.

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 June 14, 2019.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015260 - SE0015263 were determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product[1] Found SE Under:	SE Order Date
SE0015260	Marlboro Gold Pack 100's Box	SE0012348	December 1, 2015
SE0015261	Marlboro Silver Pack Box	SE0012351	December 1, 2015
SE0015262	Marlboro Silver Pack 100's Box	SE0012350	December 1, 2015
SE0015263	Marlboro Gold Pack 100's Box	SE0012348	December 1, 2015

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 section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated August 7, 2019, concludes that the new tobacco products are in compliance with the FD&C Act.

[1]SE0012348, SE0012351, and SE0012350 were previously submitted as SE0009428, SE0009430, and SE0009429, respectively, which received SE orders on June 16, 2015. After receiving SE orders, the applicant notified FDA that there were errors in the ingredient information due to miscalculations. The applicant provided revised ingredient quantities and calculations (see TC0001329). FDA reviewed the information and determined that the changes created distinctly different new and predicate tobacco products and that submission of new SE Reports was required. The applicant subsequently submitted SE0012348, SE0012351, and SE0012350, which they certified were identical to SE0009428, SE0009430, and SE0009429, respectively, with the exception of the revised (b) (4) ingredient quantities. Since the SE orders for SE0009428, SE0009430, and SE0009429 were based upon incorrect information about the characteristics of the new and predicate tobacco products, these orders were rescinded. In addition, because the information in both sets of SE Reports (other than the ingredient information as noted by the applicant) was identical, a decision was made to duplicate the FDA work products from SE0009428, SE0009430, and SE0009429 in the official archive and the Office of Science database. As a result, the scientific reviews for SE0012348, SE0012351, and SE0012350 reference SE0009428, SE0009430, and SE0009429, respectively. Chemistry review was the only new scientific review that was conducted for SE0012348, SE0012351, and SE0012350 to analyze the revised ingredient information from the applicant.

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 Karina Zuck on July 31, 2019. A chemistry addendum review was completed by Karina Zuck on September 3, 2019.

The chemistry review and the addendum review conclude that the new tobacco products have different characteristics related to product chemistry 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:

- SE0015260, SE0015263
  - Ingredients:
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Decrease in filter tow ingredients [(b) (4) (71%), (b) (4) (63%), (b) (4) (24%), and (b) (4) (49%)]
    - 67% increase in (b) (4) and (b) (4)
    - 233% increase in (b) (4) in cigarette paper
- SE0015261
  - Ingredients:
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - 17% increase in (b) (4)
    - 70% increase in (b) (4) and (b) (4)
    - 250% increase in (b) (4)
  - Tar, Nicotine, and Carbon Monoxide (TNCO) and Harmful and Potentially Harmful Constituents (HPHCs):
    - Decrease in tar (12%, ISO) and carbon monoxide (17%, ISO)
    - Decrease in crotonaldehyde (23%, ISO)
- SE0015262
  - Ingredients:
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - Addition of (b) (4) ((b) (4) mg/cig)
    - 17% increase in (b) (4)
    - 67% increase in (b) (4) and (b) (4)
    - 233% increase in (b) (4) in cigarette paper
  - TNCO and HPHCs:
    - Decrease in tar (15%, ISO) and carbon monoxide (19%, ISO)
    - Decrease in crotonaldehyde (34%, ISO) and toluene (26%, ISO)

The applicant included certification statements indicating that the only changes between the new and predicate tobacco products are in the cigarette paper, base tipping paper, tipping adhesive, and filter tow.[2] In all the SE Reports, (b) (4), and (b) (4) are present in the new tobacco products, but not in the corresponding predicate tobacco products. The presence of (b) (4), and (b) (4) are small enough to not cause measurable changes in smoke chemistry. In all the SE Reports, (b) (4) and (b) (4) are 67-70% higher in the new tobacco products compared to the corresponding predicate tobacco products and (b) (4) is 233-250% higher in the new tobacco products compared to the corresponding predicate tobacco products. Increases in (b) (4) and (b) (4) can accelerate burning by increasing the static burn rate and reducing the number of puffs per cigarette which, in turn, can decrease tar and affect the level of carbon monoxide. Increases in (b) (4) may affect the production of some HPHCs such as formaldehyde, benzo[a]pyrene (B[a]P), benzene, acetaldehyde, and styrene. In SE0015261 and SE0015262, the total amount of (b) (4) in the cigarette paper and tipping paper is 17% higher in the new tobacco products compared to the corresponding predicate tobacco products. Increases in (b) (4) in the tipping paper may lead to an increase in HPHCs such as acetaldehyde, formaldehyde and benzene, which are the potential pyrolysis products from thermal degradation of (b) (4). Several ingredients in the filter tow were decreased in the new tobacco products compared to the predicate tobacco products in SE0015260 and SE0015263, which does not cause the new tobacco products to raise different questions of public health because these changes are not expected to substantially affect the filter efficiency. The quantities of (b) (4) (b) (4), and (b) (4), and the change in the filter tow ingredients in the new tobacco products compared to the corresponding predicate tobacco products did not lead to increases in HPHC yields that would raise different questions of public health. Therefore, from a chemistry perspective, the differences in ingredients in the new tobacco products do not cause the new tobacco products to raise different questions of public health.

The applicant submitted data for TNCO and seven HPHCs measured under ISO and Canadian Intense (CI) smoking regimens for the new and corresponding predicate tobacco products. With the exception of tar, CO, crotonaldehyde, and toluene[3] in SE0015261 and SE0015262 under the ISO regimen, which all decreased, all HPHCs were analytically equivalent using the two one-sided t-test (TOST).[4] The decreases in tar, CO, crotonaldehyde, and toluene[3] do not cause the new tobacco products in SE0015261 and SE0015262 to raise different questions of public health from a chemistry perspective; however, these decreases are not analytically equivalent and were deferred to toxicology for evaluation.

There is an increase in cigarette paper band porosity and a decrease in cigarette paper band width in all the new tobacco products and an increase in filter total denier in the new tobacco products in SE0015260 and SE0015263 compared to the corresponding predicate tobacco products. Changes in band porosity, band width, and total denier could affect the levels of TNCO and B[a]P (engineering defers the evaluation of TNCO and B[a]P due to these changes to chemistry). However, the levels of TNCO and B[a]P are either lower or analytically equivalent

[2] SE0015260 and SE0015263 only

[3] SE0015262 only

[4] See April 16, 2019, Addendum to the February 24, 2017, Equivalence Testing for SE Evaluations Memorandum

between the new tobacco products and the corresponding predicate tobacco products. From a chemistry perspective, the changes in band porosity, band width, and total denier in the new tobacco products do not 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 from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Pritesh Darji on August 16, 2019.

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:

- Cigarette paper band porosity (↑125%)
- Cigarette paper band width (↓8%)
- Total denier (↑6%) (SE0015260 and SE0015263 only)

In all SE Reports, cigarette paper band porosity increases (125%) and cigarette paper band width decreases (8%) in the new tobacco products in comparison to the corresponding predicate tobacco products. Such differences may lead to a decrease in TNCO, but an increase in B[a]P. Additionally, in SE0015260 and SE0015263, total denier increases (6%) in the new tobacco products in comparison to the predicate tobacco products. Such differences may lead to a decrease in tar, nicotine and B[a]P. Engineering deferred the evaluation of the impact of the change in cigarette paper band porosity, cigarette paper band width and total denier on TNCO and B[a]P smoke data to chemistry (see chemistry section above).

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 Eric Beier on July 31, 2019.

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

- Change in the tipping paper composition
  - (b) (4) (↑90%), (b) (4) (↑6%), (b) (4) (↑9%), (b) (4) (↑1000%), (b) (4) (added), (b) (4) (added), (b) (4) (added)
- Change in the and tipping adhesive composition
  - (b) (4) (added)
- Change in the cigarette paper composition
  - (b) (4) (↑25%), (b) (4) (↑67%), (b) (4) (↑67%), (b) (4) (↑233%)[6], (b) (4) (added)

Although there are increased levels of (b) (4) and (b) (4) these components are in a physical form that is not expected to cause any toxic effects. In addition, they are expected to be bound to the paper and release from that medium is expected to be negligible. Therefore, exposure via the inhalation, oral, or dermal route to ingredients in the tipping paper is expected to be minimal during normal cigarette consumption. In addition, the tipping paper is in the non-combusted part of the cigarette and it is not expected to be burned, volatilized, or to be a potential source of thermal degradation resulting in the release of HPHCs in cigarette smoke. Similarly, no toxicity is expected from increased levels of (b) (4) and (b) (4) (b) (4) as these ingredients are in the non-combusted part of the cigarette. Thus, the addition and increases of (b) (4) and the other listed ingredients in the new tobacco products are not of toxicological concern when the products are used normally. Therefore, for the tipping paper and tipping adhesive, assessment of the ingredient changes suggests that while there are differences between the new tobacco products and the corresponding predicate tobacco products, they do not cause the new tobacco products to raise different questions of public health from a toxicological perspective. With regard to ingredient changes in the cigarette paper, these changes may lead to changes in HPHCs. Chemistry deferred evaluation of the decreases in tar, CO, and crotonaldehyde in the new tobacco products in SE0015261 and SE0015262 as well as the decrease in toluene in the new tobacco product in SE0015262 to toxicology. Because there were no substantial increases in TNCO and selected HPHCs, this suggests that the new tobacco products have a toxicity profile that is similar to that of the corresponding predicate tobacco products. Therefore, the changes in cigarette paper, tipping paper, and tipping adhesive do not 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 from a toxicology perspective.

[5] The toxicology review inadvertently listed this as (b) (4) rather than (b) (4)
[6] The toxicology review inadvertently listed this as a 333%

5. ENVIRONMENTAL DECISION

An environmental review was completed by Mehran Niazi on July 10, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 22, 2019. The FONSI was supported by an environmental assessment prepared by FDA on July 22, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Filter tow (SE0015260 and SE0015263 only)
  - Increase in total denier (6%)
  - Decrease in filter tow ingredients [(b) (4) (71%), (b) (4) (63%), (b) (4) (24%), and (b) (4) (49%)]
- Tipping paper composition
  - Increase in (b) (4) (90%), (b) (4) (6%), (b) (4) (9%), and (b) (4) (1000%)
  - Addition of (b) (4) and (b) (4)
- Tipping adhesive composition
  - Addition of (b) (4)
- Cigarette paper composition and design
  - Increase in (b) (4) (25%), (b) (4) (67%), (b) (4) (67%), and (b) (4) (233%)
  - Addition of (b) (4)
  - Increase in cigarette paper band porosity (125%)
  - Decrease in cigarette paper band width (8%)
- TNCO and HPHCs
  - Decrease in tar (12% ISO, SE0015261; 15% ISO, SE0015262) and carbon monoxide (17% ISO, SE0015261, 19% ISO, SE0015262)
  - Decrease in crotonaldehyde (23% ISO, SE0015261, 34% ISO SE0015262) and toluene (26% ISO, SE0015262)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant included certification statements indicating that the only changes between the new and corresponding predicate tobacco products are in the cigarette paper, base tipping paper, tipping adhesive, and filter tow.[2] Although some design parameter changes were identified in the cigarette paper and filter tow, which may lead to changes in TNCO and B[a]P, the levels of these HPHCs are either analytically equivalent or lower in the new tobacco products as compared to the corresponding predicate tobacco products. While numerous ingredients were changed or added in the tipping paper, tipping adhesive, and cigarette paper, any differences in TNCO and selected HPHCs (acetaldehyde, acrolein, benzene, B[a]P, crotonaldehyde, formaldehyde and toluene) were either within the analytical variability of the methods or there were no significant increases and, thus, do not cause the new tobacco products to raise different questions of public health. The levels of ingredients added or increased in the tipping paper and cigarette paper are not expected to cause an increased level of exposure via the

inhalation, oral, or dermal routes in comparison to the corresponding predicate tobacco products. Consequently, the changes in the filter tow, tipping paper and adhesive composition, cigarette paper composition and design, and changes to HPHCs suggest that the toxicity profile of the new tobacco products is similar to that of the corresponding predicate tobacco products. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products in SE0015260, SE0015261, SE0015262, and SE0015263 were previously determined to be substantially equivalent by FDA under SE0012348, SE0012351, SE0012350, and SE0012348, respectively.

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 product in SE0015260 and SE0015263 was previously determined to be substantially equivalent by FDA under SE0012348. Comparison of the new tobacco products in SE0015260 and SE0015263 to the grandfathered tobacco product (GF1200092, Marlboro Lights 100's Box) reveals that the new tobacco products have the following differences in characteristics from the grandfathered tobacco product:

- Design Parameters
  - Increase in cigarette paper band space (0.46%)
  - Decrease in filter ventilation (2% absolute change)
- Ingredients
  - Change in citrates (b) (4) (↑300%), (b) (4) (↓55%), and (b) (4) (removed)] in the cigarette paper
  - Increase in (b) (4) (5%) in the cigarette paper
  - Addition of (b) (4), and (b) (4) in the cigarette paper bands
  - 44% decrease in (b) (4)
  - Addition of (b) (4) to the tipping base paper
  - Addition of (b) (4)
  - Decrease in (b) (4) (20) (b) (4) (87%), (b) (4) (83%), (b) (4) (10%), and increase in (b) (4) (64%) in the filter tow

The differences in cigarette paper and cigarette paper band characteristics listed above are similar to the differences in characteristics identified for the new and grandfathered tobacco products in SE0012348. The changes to the design parameters that have been provided for both the new and grandfathered tobacco products are small and are not anticipated to have a measurable impact on smoke chemistry. The ingredient changes to the cigarette paper and cigarette paper bands noted in the bullet points above are not expected to have a measurable impact on the levels of HPHCs when comparing the new tobacco products to the grandfathered tobacco product. A TNCO comparison between the new and grandfathered tobacco products reveals that TNCO levels are analytically equivalent. Consequently, the ingredient differences between the new and predicate tobacco products represent similar differences as between the new and grandfathered tobacco products. Therefore,

these differences do not cause the new tobacco products in SE0015260 and SE0015263 to raise different questions of public health. Thus, the differences in design parameters, ingredients, and HPHCs between the new tobacco products in SE0015260 and SE0015263 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015260 and SE0015263 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

The differences in cigarette paper and cigarette paper band characteristics listed above are similar to the differences in characteristics identified for the new and grandfathered tobacco products in SE0012350. The changes to the design parameters that have been provided for both the new and grandfathered tobacco products are not anticipated to have a measurable impact on smoke chemistry. The ingredient changes to the cigarette paper and cigarette paper bands noted in the bullet points above are not expected to have a measurable impact on the levels of HPHCs when comparing the new tobacco products to the grandfathered tobacco product. A TNCO comparison between the new and grandfathered tobacco products reveals that tar levels are analytically equivalent and nicotine and carbon monoxide have decreased. Consequently, the ingredient differences between the new and predicate tobacco products represent similar differences as between the new and grandfathered tobacco products. Therefore, these differences do not cause the new tobacco product in SE0015262 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in design parameters, ingredients, and HPHCs between the new tobacco product in SE0015262 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 SE0015262 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015261 was previously determined to be substantially equivalent by FDA under SE0012351. Comparison of the new tobacco product to the grandfathered tobacco product (GF1200102, Marlboro Ultra Lights Box) in SE0012351 reveals that the new tobacco product has the following differences in characteristics from Marlboro Ultra Lights Box, the grandfathered tobacco product:

- Design Parameters
  - Increase in cigarette paper band space (0.46%)
- Ingredients
  - Change in citrates [(b) (4)] (↓55%), [(b) (4)] (added), and [(b) (4)] (removed)] in the cigarette paper
  - Decrease in [(b) (4)] (15%) in the cigarette paper
  - Increase in [(b) (4)] (5%) in the cigarette paper
  - Addition of [(b) (4)], and [(b) (4)] to the cigarette paper bands
  - 425% increase in [(b) (4)]
  - Addition of [(b) (4)] to the tipping base paper
- Decrease in nicotine (16% ISO) and carbon monoxide (11% ISO)

The differences in cigarette paper and cigarette paper band characteristics listed above are similar to the differences in characteristics identified for the new and grandfathered tobacco products in SE0012351. The changes to the design parameters that have been provided for both the new and grandfathered tobacco products are not anticipated to have a measurable impact on smoke chemistry. The ingredient

changes to the cigarette paper and cigarette paper bands noted in the bullet points above are not expected to have a measurable impact on the levels of HPHCs when comparing the new tobacco products to the grandfathered tobacco product. A TNCO comparison between the new and grandfathered tobacco products reveals that tar levels are analytically equivalent and nicotine and carbon monoxide have decreased. Consequently, the ingredient differences between the new and predicate tobacco products represent similar differences as between the new and grandfathered tobacco products. Therefore, these differences do not cause the new tobacco product in SE0015261 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in design parameters, ingredients, and HPHCs between the new tobacco product in SE0015261 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 SE0015261 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015262 was previously determined to be substantially equivalent by FDA under SE0012350. Comparison of the new tobacco product to the grandfathered tobacco product (GF1200101, Marlboro Ultra Lights 100's Box) in SE0012350 reveals that the new tobacco product has the following differences in characteristics from Marlboro Ultra Lights 100's Box, the grandfathered tobacco product:

- Design Parameters
  - Increase in cigarette paper band space (0.46%)
- Ingredients
  - Change in citrates [(b) (4) (↓55%), (b) (4) (added), and (b) (4) (removed)] in the cigarette paper
  - Decrease in (b) (4) (15%) in the cigarette paper
  - Increase in (b) (4) (5%) in the cigarette paper
  - Addition of (b) (4), and (b) (4) to the cigarette paper bands
  - Addition of (b) (4)
  - 400% increase in (b) (4)
  - Addition of (b) (4) to the tipping base paper
- Decrease in nicotine (16% ISO) and carbon monoxide (11% ISO)

The differences in cigarette paper and cigarette paper band characteristics listed above are similar to the differences in characteristics identified for the new and grandfathered tobacco products in SE0012350. The changes to the design parameters that have been provided for both the new and grandfathered tobacco products are not anticipated to have a measurable impact on smoke chemistry. The ingredient changes to the cigarette paper noted in the bullet points above are not expected to have a measurable impact on the levels of HPHCs when comparing the new tobacco products to the grandfathered tobacco product. A TNCO comparison between the new and grandfathered tobacco products reveals that tar levels are analytically equivalent and nicotine and carbon monoxide have decreased. Consequently, the ingredient differences between the new and predicate tobacco products represent similar differences as between the new and grandfathered tobacco products. Therefore, these differences do not cause the new tobacco product in SE0015262 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in design parameters, ingredients, and HPHCs between the new tobacco product in SE0015262 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 SE0015262 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act. 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 SE0015260, SE0015261, SE0015262, and SE0015263, as identified on the cover page of this review.