FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0014618, SE0014619, SE0014621, and SE0014622

| SE0014618: Top Premier Blue King Size | |
|---|---|
| Package Type | Box |
| Package Quantity | 200 Tubes |
| Length | 84 mm |
| Diameter | 8.2 mm |
| Ventilation | 35% |
| Characterizing Flavor | None |
| **SE0014619: Top Premier Blue 100MM** | |
| Package Type | Box |
| Package Quantity | 200 Tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | None |
| **SE0014621: Top Premier Regular 100MM** | |
| Package Type | Box |
| Package Quantity | 200 Tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | None |
| **SE0014622: Top Premier Menthol King Size** | |
| Package Type | Box |
| Package Quantity | 200 Tubes |
| Length | 84 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | Menthol |
| **Common Attributes of SE Reports** | |
| Applicant | Republic Tobacco, LP |
| Report Type | Regular |
| Product Category | Roll-Your-Own Tobacco Products |
| Product Sub-Category | Filtered Cigarette Tube |
| **Recommendation** | |
| Issue Substantially Equivalent (SE) orders. | |

**Technical Project Lead (TPL):**

Digitally signed by Shixia Feng -S
Date: 2019.04.08 15:39:07 -04'00'

Shixia Feng, Ph.D.
Chemistry 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: 2019.04.08 18:04:42 -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:

| | |
|---|---|
| **SE0014618: Top Premier Blue King Size** | |
| Product Name | Top Regular 100MM |
| Package Type | Box |
| Package Quantity | 200 tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | None |
| **SE0014619: Top Premier Blue 100MM** | |
| Product Name | Top Gold 100MM |
| Package Type | Box |
| Package Quantity | 200 tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | None |
| **SE0014621: Top Premier Regular 100MM** | |
| Product Name | Top Regular 100MM |
| Package Type | Box |
| Package Quantity | 200 tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | None |
| **SE0014622: Top Premier Menthol King Size** | |
| Product Name | Top Menthol King Size |
| Package Type | Box |
| Package Quantity | 200 tubes |
| Length | 84 mm |
| Diameter | 8.2 mm |
| Ventilation | 0% |
| Characterizing Flavor | Menthol |

The predicate tobacco products are roll-your-own (RYO) filtered cigarette tubes manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 12, 2018, FDA received four SE Reports from Republic Tobacco, LP (SE0014618, SE0014619, SE0014621, SE0014622). On April 19, 2018, FDA issued Acknowledgement letters to the applicant. On July 3, 2018, FDA issued an Advice/Information (A/I) Request letter. On July 5, 2018, the applicant contacted FDA with a question regarding the A/I Request letter, and FDA provided the clarification. On August 16, 2018, FDA received the response to the A/I Request letter (SE0014854). On November 2, 2018, FDA issued a Preliminary Finding (Pfind) letter. On January 10, 2019, FDA received the response to the Pfind letter (SE0015048).

| Product Name | SE Report | Amendments |
|---|---|---|
| Top Premier Blue King Size | SE0014618 | SE0014854<br>SE0015048 |
| Top Premier Blue 100MM | SE0014619 | |
| Top Premier Regular 100MM | SE0014621 | |
| Top Premier Menthol King Size | SE0014622 | |

### 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 Nicholas Hasbrouck on April 19, 2018.

The reviews conclude that the SE Reports are administratively complete.

## 3. COMPLIANCE REVIEW

The predicate tobacco products in SE0014618, SE0014619, SE0014621, and SE0014622 were previously 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 Found SE Under: | Date |
|---|---|---|---|
| SE0014618 | Top Regular 100MM | SE0003200 | September 26, 2013 |
| SE0014619 | Top Gold 100MM | SE0003199 | September 26, 2013 |
| SE0014621 | Top Regular 100MM | SE0003200 | September 26, 2013 |
| SE0014622 | Top Menthol King Size | SE0012366 | December 18, 2017 |

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 reviews dated October 29, 2018 and April 3, 2019, 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

Chemistry reviews were completed by John Gong on June 7, 2018 and October 2, 2018. Additionally, John Gong completed a chemistry review on March 11, 2019 to address the statutory requirement that 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 (grandfathered (GF) product) (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The final chemistry review concludes that the four new tobacco products have different characteristics related to product composition compared to the corresponding predicate tobacco products (previously found SE) as well as the grandfathered tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following significant differences in chemistry characteristics in the new products compared to the corresponding predicate products:[1]

- Addition of (b) (4) in the cigarette paper (SE0014619)
- Increase in (b) (4) in the filter (SE0014619)
- Increases in (b) (4) in the tipping paper (SE0014618, SE0014621, and SE0014622)
- Addition of 5.28-5.65 mg (b) (4) in the tipping glue (SE0014618, SE0014619, and SE0014621)

The final chemistry review also identified the following significant characteristics differences in the new products compared to the corresponding grandfathered products:

- Increases in (b) (4) in the cigarette paper (SE0014618, SE0014619, and SE0014621)
- Increases in (b) (4) in cigarette paper (SE0014619 and SE0014621)
- Decrease in (b) (4) SE0014622)
- Increases in filter tube mass (SE0014619 and SE0014621)
- Increases in filter tube length (SE0014619 and SE0014621)
- Increases in denier per filament (SE0014619 and SE0014621)
- Decreases in denier per filament (SE0014618 and SE0014622)
- Increases in filter pressure drop (SE0014618, SE0014619, SE0014621, and SE0014622)
- Increases in (b) (4) in cigarette paper (SE0014618, SE0014619, SE0014621)
- Decrease in (b) (4) (SE0014618)

[1] The 2nd round chemistry review concluded that there was an increase in (b) (4) for SE0014619. This was an error and therefore, should not be listed as a significant difference for SE0014619. Additionally, the 2nd round chemistry review also concluded there were increases in (b) (4) in the tipping paper and (b) (4) for SE0014618 and SE0014621. The correct identification of the differences should be increases in (b) (4) in the tipping paper for SE0014618, SE0014621, and SE0014622.

- Increases in paper base paper porosity (SE0014618 and SE0014619)

The applicant addressed the increase in [redacted] in the new tobacco product (SE0014619) compared to the predicate tobacco products by providing formaldehyde, acetaldehyde, and benzene test data collected from RYO test cigarettes which were filled with the same tobacco at the same packing density. Formaldehyde, acetaldehyde, and benzene were measured under both ISO and CI smoking regimens using acceptable analytical methods. The average levels of formaldehyde, acetaldehyde, and benzene in the new products are either lower or within the expected analytical variability of the analytical methods compared to the corresponding predicate tobacco products. In addition, the applicant reported higher amounts of [redacted] (SE0014619) and [redacted] (SE0014618, SE0014621, and SE0014622), and addition of [redacted] (SE0014618, SE0014619, and SE0014621) in the new tobacco products compared to the predicate tobacco products. However, these ingredients are contained in the non-combusted parts of the tobacco product and are unlikely to raise different questions of public health from a chemistry perspective. Therefore, the differences in characteristics related to product composition between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

After the completion of the 2nd round of scientific review, a TPL Review was conducted on October 23, 2018 that identified some differences between the new and corresponding grandfathered tobacco products. Compared to the grandfathered tobacco products, the new tobacco products have changes that could increase the HPHC yields. Such changes include increases in [redacted] (SE0014618, SE0014619, and SE0014621), [redacted] in cigarette paper (SE0014619 and SE0014621), denier per filament (SE0014619 and SE0014621), and filter tube mass and tube length (SE0014619 and SE0014621), and a decrease in [redacted] (SE0014622). On the other hand, the new tobacco products also have changes that could decrease the HPHC yields. Such changes include decreases in [redacted] SE0014618) and denier per filament (SE0014618 and SE0014622); increases in [redacted] in cigarette paper (SE0014618, SE0014619, SE0014621), filter pressure drop (SE0014618, SE0014619, SE0014621, and SE0014622), and paper base paper porosity (SE0014618 and SE0014619). Therefore, the overall effects of differences between the new and grandfathered products are unclear. The TPL Review contained a deficiency requesting additional TNCO yields as a potential way to provide scientific evidence. In response to the Pfind letter, the applicant provided TNCO test data collected from RYO test cigarettes which were filled with the same tobacco at the same packing density. TNCO were measured under ISO smoking regimens using acceptable analytical methods. The average levels of TNCO in the new products are either lower or within the expected analytical variability of the analytical methods compared to the corresponding grandfathered products. Therefore, these differences in characteristic differences between the new and grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

## 4.2. ENGINEERING

Engineering reviews were completed by Michael Morschauser on May 22, 2018, and September 20, 2018.

For SE0014619, the final engineering review did not identify any differences in characteristics between the new and corresponding predicate products that could cause the new product to raise different questions of public health.

For SE0014618, SE0014621, and SE0014622, the final engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

SE0014618

- Decrease in filtered tube length (16%)
- Decrease in tipping paper length (14%)
- Decrease in filtered tube mass (28%)
- Increase in tube paper base paper porosity (100%)
- Decrease in filter denier per filament (28%)
- Addition of filter ventilation (35%)
- Increase in filter density (7%)
- Decrease in filter pressure drop (10%)
- Decrease in filter length (40%)

SE0014621

- Increase in filter density (7%)
- Increase in filter pressure drop (14%)

SE0014622

- Decrease in filtered tube mass (6%)
- Decrease in filter total denier (6%)
- Decrease in filter denier per filament (14%)
- Decrease in filter density (6%)

The new and corresponding predicate tobacco products have differences in product design parameters for SE0014618, SE0014621, and SE0014622; however, these differences do not cause the new products to raise different questions of public health. Specifically, for SE0014618, the new tobacco product has decreases in filtered tube length, filtered tube mass, and filter denier per filament, increases in tube paper base paper porosity and filter density, and the addition of filter ventilation, all of which may decrease HPHC yields; however, the new product also has decreases in filter pressure drop and filter length which may increase tar and nicotine yields. For SE0014621, the new product has increases in filter density and filter pressure drop which may decrease tar and nicotine yields. For SE0014622, the new product has decreases in filter tube mass and filter denier per filament, which may decrease HPHC yields; however, the new product also has decreases in filter total denier and filter density which may increase tar and nicotine yields. The applicant provided TNCO data for the new and corresponding predicate products in SE0014618, SE0014621, and SE0014622, which showed either decreased or similar levels of TNCO (the evaluation of TNCO data is deferred to Chemistry), demonstrating the many differences in design parameters between the new and corresponding predicate tobacco products do not cause the new 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 related to product engineering.

### 4.3. TOXICOLOGY

Toxicology reviews were completed by Kamau Peters on June 19, 2018, and October 4, 2018.

For SE0014622, the final toxicology review did not identify any differences in characteristics between the new and corresponding predicate product that could cause the new product to raise different questions of public health. For SE0014618, SE0014619, and SE0014621, 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:

- Higher level in formaldehyde (SE0014619)
- 33-67% lower amount of rod print ink ingredients (SE0014618, SE0014619, SE0014621)

Although there are differences in ingredients between the new and predicate tobacco products, the applicant provided adequate evidence to demonstrate that the ingredient differences do not cause the new products to raise different questions of public health. As discussed in the chemistry review, the increase in formaldehyde (5.3%) was smaller than the expected analytical variability of the analytical methods, and therefore, does not raise concerns from a toxicological perspective. The lower amount of ink ingredients are not a toxicological concern because it will not increase HPHC yields. 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 toxicology.

## 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Rudaina Alrefai-Kirkpatrick on June 7, 2018, August 31, 2018, and January 28, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 14, 2018. The FONSI was supported by an environmental assessment prepared by FDA on November 14, 2018.

## 6. CONCLUSION AND RECOMMENDATION

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

- Higher amounts of (b) (4) in the cigarette paper (SE0014619)
- Higher amounts of (b) (4) in the filter (SE0014619)

- Higher amounts of [redacted] in the tipping paper and [redacted] (SE0014618, SE0014621, and SE0014622)
- Addition of 5.28-5.65 mg [redacted] in the tipping glue (SE0014618, SE0014619, and SE0014621)
- 33-67% lower amount of rod print ink ingredients (SE0014618, SE0014619 and SE0014621)
- 16% decrease in filtered tube length (SE0014618)
- 14% decrease in tipping paper length (SE0014618)
- 6%-28% decrease in filtered tube mass (SE0014618 and SE0014622)
- 100% increase in tube paper base paper porosity (SE0014618)
- 14-28% decrease in filter denier per filament (SE0014618 and SE0014622)
- 35% addition of filter ventilation (SE0014618)
- 7% increase in filter density (SE0014618 and SE0014621)
- 10% decrease in filter pressure drop (SE0014618)
- 40% decrease in filter length (SE0014618)
- 6% decrease in filter total denier (SE0014622)
- 6% decrease in filter density (SE0014622)
- 14% increase in filter pressure drop (SE0014621)

The applicant has demonstrated that these differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. The new product of SE0014619 contains higher amount of [redacted] which may increase the yields of formaldehyde, acetaldehyde, and benzene due to pyrolysis. The applicant addressed the issue of higher amounts of [redacted] by providing formaldehyde, acetaldehyde, and benzene test data measured under both ISO and CI smoking regimens using acceptable analytical methods. The average levels of formaldehyde, acetaldehyde, and benzene in the new tobacco products are either lower or within the expected analytical variability of the analytical methods compared to the corresponding predicate tobacco products. There are higher amounts of [redacted] (SE0014619) and [redacted] (SE0014618, SE0014621, and SE0014622), and addition of [redacted] in the new tobacco products (SE0014618, SE0014619, and SE0014621). However, these ingredients are contained in the non-combusted parts of the tobacco product and therefore, do not result in increased TNCO yields. Addtionally, the amount of rod print ink ingredients are lower in the new products of SE0014618, SE0014619, and SE0014621, which is not expected to result in increase in HPHC yields as well.

Except for SE0014619 (no significant design changes), there are many design changes for these SE Reports, some of which may decrease the HPHC yields due to enhanced filter efficiency (e.g., by increasing filter density, decreasing filter denier per filatment, or increasing total denier), or dilution of mainstream smoke (by increasing in filter ventilation or cigarette paper base paper porosity), or less materials to burn (e.g., by decreasing tube length or or tube mass); whereas other changes may have the opposite effect. Specifically, for SE0014618, the new tobacco product has decreases in filtered tube length, filtered tube mass, and filter denier per filament, an increase in tube paper base paper porosity and filter density, and the addition of filter ventilation, all of which may decrease smoke yields; however, the new product also has decreases in filter pressure drop and filter length which may increase tar and nicotine yields. For SE0014621, increases in filter density and filter pressure drop would only result in decrease in HPHC yields. For SE0014622, the new product has decreases in filter tube mass and filter denier per filament, which may decrease smoke yields; however, the new product also has decreases in filter total denier and filter density which may

increase tar and nicotine yields. The overall effect of these design changes in SE0014618 and SE0014622 are evaluated through the TNCO data for the new and corresponding predicate products, which showed either decreased or similar levels of TNCO, demonstrating the many differences in design parameters between the new and corresponding predicate tobacco products do not cause the new products 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 SE0014618 and SE0014621 was determined to be substantially equivalent by FDA under SE0003200. Additionally, the predicate tobacco products in SE0014619 and SE0014622 were determined to be substantially equivalent by FDA under SE0003199 and SE0012366, 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 products in SE0014618 and SE0014621 were previously determined to be substantially equivalent by FDA under SE0003200, and SE0014619 and SE0014622 were previously determined to be substantially equivalent by FDA under SE0003199 and SE0012366, respectively. Comparison of the new tobacco products to the grandfathered products (Top Regular King Size in SE0003200, Top Menthol King Size in SE0012366, and Top Gold King Size in SE0003199) reveals that the new tobacco products have the following differences in characteristics from Top Regular King Size, Top Menthol King Size, and Top Gold King Size, the grandfathered tobacco products:

SE0014618

- 13% increase in (b) (4) in the cigarette paper
- 57% increase in (b) (4) in cigarette paper
- 14% decrease in (b) (4) in cigarette paper
- 43% decrease in (b) (4) in filter
- Addition of 5.28 mg of (b) (4) in tipping glue
- 445% increase in (b) (4) in tipping paper
- 6% decrease in filter tube mass
- 100% increase in paper base paper porosity
- 5% decrease in denier per filament
- 6% increase in filter pressure drop

For SE0014618, compared to the grandfathered product, the increases in paper base paper porosity and filter pressure drop as well as decreases in denier per filament, tube mass and (b) (4) m in cigarette paper, are expected to decrease the HPHC yields. Additionally, an increase in (b) (4) in cigarette paper could accelerate the burn rate and therefore, may decrease the puff count and tar. However, there is also an increase in (b) (4) in cigarette paper and a decrease in (b) (4) in filter (potentially negatively impact the fitler efficiency) that may increase smoke yields. Increases in (b) (4) in tipping paper and (b) (4) in tipping glue are not expected to affect HPHC yields since these ingredients are not combusted. The applicant provided TNCO yields between the new and grandfathered product which showed decreases in TNCO. Thus, the

differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014619

- 17% increase in (b) (4) in cigarette paper
- 11% increase in (b) (4) ate in the cigarette paper
- 198% increase in (b) (4) in cigarette paper
- 57% increase in (b) (4) in filter
- 29% increase in (b) (4) in filter
- Addition of 5.65 mg of (b) (4) in tipping glue
- 19% increase in filter tube length
- 34% increase in filter tube mass
- 93% increase in paper base paper porosity
- 32% increase in denier per filament
- 33% increase in filter pressure drop
- 67% increase in filter length

For SE0014619, compared to the grandfathered product, an increase in filter tube length results in increases in tube mass and cigarette paper ingredients (e.g., (b) (4), which may increase the HPHC yields. Additionally, an increase in denier per filament may negatively affect the filter efficiency. However, there are other factors that may reduce HPHC yields such as increases in (b) (4) (a burn modifier which may accelerate the burn rate), paper base paper porosity, filter (b) (4) and (b) (4) filter length and filter pressure drop. (b) (4) in tipping glue is not expected to affect HPHC yields. The applicant provided TNCO yields between the new and grandfathered product which showed decreases in TNCO. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014621

- 12% increase in (b) (4) in cigarette paper
- 29% increase in (b) (4) in the cigarette paper
- 79% increase in (b) (4) e in cigarette paper
- 59% increase in (b) (4) in filter
- 7.5% decrease in (b) (4) in filter
- Addition of 5.65 mg of (b) (4) in tipping glue
- 19% increase in filter tube length
- 31% increase in filter tube mass
- 32% increase in denier per filament
- 33% increase in filter pressure drop
- 67% increase in filter length

For SE0014621, compared to the grandfathered product, an increase in filter tube length results in increases in tube mass and cigarette paper ingredients (e.g., (b) (4)), which may increase the HPHC yields. Additionally, an increase in denier per filament and a decrease in filter (b) (4) may negatively affect the filter efficiency. However, there are other factors that may reduce HPHC yields such as increases in (b) (4) (a burn modifier which may accelerate the burn rate and reduce puff count), (b) (4), filter length and filter pressure drop. Addition o (b) (4) in

tipping glue is not expected to affect HPHC yields. The applicant provided TNCO yields between the new and grandfathered product which showed slight increases in tar, nicotine, and carbon monoxide, but these increases are within the variability of the measurements. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014622

- 5% decrease in (b) (4) ow in filter
- 12% decrease in (b) (4) in filter
- 35% decrease in (b) (4) in tipping glue
- 14% decrease in denier per filament
- 6% increase in filter pressure drop

For SE0014622, compared to the grandfathered product, a decrease in denier per filament and an increase in filter pressure drop may result in improved filter efficiency, which in turn may decrease HPHC yields. However, there are decreases in (b) (4), which could potentially decrease filter efficiency. Addition of (b) (4) in tipping glue is not expected to affect HPHC yields. The applicant provided TNCO yields between the new and grandfathered product which showed a slight increase in carbon monoxide, but this increase is within the variability of the measurements. The testing data also showed decreases in tar and nicotine yields. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to 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 SE0014618, SE0014619, SE0014621, and SE0014622, as identified on the cover page of this review.