

Technical Project Lead (TPL) Review: SE0009624-SE0009632 and SE0009634-SE0009647

SE0009624: Toque Snuff Black Cherry	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Black Cherry
SE0009625: Toque Snuff Chocolate	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Chocolate
SE0009626: Toque Snuff Citrus	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Citrus
SE0009627: Toque Snuff Espresso	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Espresso
SE0009628: Toque Snuff Kentucky Bourbon	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Kentucky Bourbon
SE0009629: Toque Snuff Lime	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Lime
SE0009630: Toque Snuff Peach	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Peach

¹ Applicant stated this is not applicable

SE0009631: Toque Snuff Rum & Coke	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Rum & Coke
SE0009632: Toque Snuff Spanish Brandy	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Spanish Brandy
SE0009634: Toque Snuff Wild Berry	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Wild Berry
SE0009635: Toque Snuff Whisky & Honey	
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Whiskey & Honey
SE0009636: Silver Dollar Apricot	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Apricot
SE0009637: Silver Dollar Raspberry	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Raspberry
SE0009638: Silver Dollar Original (Bergamot)	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Bergamot
SE0009639: Silver Dollar Natural	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	None
SE0009640: Silver Dollar Cherry	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Cherry

SE0009641: Silver Dollar Spearmint	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Spearmint
SE0009642: Silver Dollar Vanilla	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Vanilla
SE0009643: Silver Dollar Blueberry	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Blueberry
SE0009644: Silver Dollar Cinnamon	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Cinnamon
SE0009645: Silver Dollar Coffee	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Coffee
SE0009646: Silver Dollar Cola	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Cola
SE0009647: Silver Dollar Licorice	
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Licorice
Common Attributes of SE Reports	
Applicant	Toque Snuff Ltd.
Report Type	Provisional
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Dry Snuff
Recommendation	
Issue Not Substantially Equivalent (NSE) Orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.12.21 13:55:38 -05'00'

Colleen K. Rogers, Ph.D.
Director
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: 2017.12.22 07:57:41 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND	6
1.1. PREDICATE TOBACCO PRODUCTS	6
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	6
1.3. SCOPE OF REVIEW	6
2. REGULATORY REVIEW	7
3. COMPLIANCE REVIEW	7
4. SCIENTIFIC REVIEW	7
5. ENVIRONMENTAL DECISION.....	7
6. CONCLUSION AND RECOMMENDATION	8
6.1. DEFICIENCIES FOR SE0009624-SE0009632 AND SE0009634-SE0009647	8

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant indicates that the predicate products are Wilsons Snuff manufactured by Wilsons & Co. (Sharrow) Ltd., but did not provide sufficient information to uniquely identify the predicate tobacco products.

SE0009624: Toque Snuff Black Cherry	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Blackberry
SE0009625: Toque Snuff Chocolate	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Chocolate
SE0009626: Toque Snuff Citrus	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Seville
SE0009627: Toque Snuff Espresso	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Coffee Cream
SE0009628: Toque Snuff Kentucky Bourbon	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Whisky
SE0009629: Toque Snuff Lime	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Lemon Toast

SE0009630: Toque Snuff Peach	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Lemon Toast
SE0009631: Toque Snuff Rum & Coke	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Rum & Raisin
SE0009632: Toque Snuff Spanish Brandy	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Brandy
SE0009634: Toque Snuff Wild Berry	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Strawberry and Cherry
SE0009635: Toque Snuff Whiskey & Honey	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	10 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Whisky and Honey Menthol
SE0009636: Silver Dollar Apricot	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Apricot
SE0009637: Silver Dollar Raspberry	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Raspberry

SE0009638: Silver Dollar Original (Bergamot)	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Spearmint
SE0009639: Silver Dollar Natural	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Plain
SE0009640: Silver Dollar Cherry	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Cherry
SE0009641: Silver Dollar Spearmint	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Spearmint
SE0009642: Silver Dollar Vanilla	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Vanilla
SE0009643: Silver Dollar Blueberry	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Blueberry
SE0009644: Silver Dollar Cinnamon	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Cinnamon

SE0009645: Silver Dollar Coffee	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided ¹
Characterizing Flavor	Coffee
SE0009646: Silver Dollar Cola	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided
Characterizing Flavor	Cola
SE0009647: Silver Dollar Licorice	
Product Name	Wilsons Snuff
Package Type	Tin
Package Quantity	5 grams
Tobacco Cut Size	Not Provided
Characterizing Flavor	Licorice

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 16, 2011, Toque Snuff Ltd. submitted 15 SE reports (b) (4) (redacted). FDA issued Acknowledgement letters on September 13, 2011. Subsequently, these reports were found administratively incomplete and an Advice/Information (A/I) Request letter was issued to the applicant on December 28, 2012. After several communications to obtain additional product information, the applicant submitted a response to FDA's requests on June 11, 2013 (b) (4) (redacted). Based on this response, FDA created 24 new STNs for the two brand styles, Toque Snuff 10 grams and Silver Dollar Snuff 5 grams, each with 12 flavors (SE0009624-SE0009647) and the SE Reports, (b) (4) (redacted) were withdrawn on January 28, 2015.

FDA acknowledged the SE Reports on September 30, 2013. FDA issued an A/I Request letter on January 13, 2014, for SE0009636-SE0009647 and on January 14, 2014, for SE0009624-SE0009632, SE0009634, and SE0009635, requesting product identification for the predicate tobacco product, the basis for substantial equivalence, and the first commercial market date for all STNs. FDA issued Notification letters on September 11, 2015, for the SE Reports, which

at scientific review was expected to begin on October 26, 2015.

uation, the Office of Compliance and Enforcement (OCE) determined

n was needed from the applicant to support the eligibility of the

informed the applicant that

During the Predicate Evalu

that additional informatio

STNs, requesting additional identifying information for the new and predicate tobacco products, a statement verifying the predicate tobacco products were not exclusively in a test market, and commercial marketing data to support the applicant's contention that the products were able to serve as predicates. The applicant did not respond to this request. When the applicant's response did not resolve the identified deficiencies, OCE conducted Independent Evidence Research (IER) as described below. OCE's IER, and the information provided by the applicant,

failed to demonstrate that the predicate tobacco products were commercially marketed, other than exclusively in test markets, as of February 15, 2007.

1.3. SCOPE OF REVIEW

This review captures all regulatory and compliance reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Kristen Jackson, M.P.H., on January 6, 2014.

The final reviews conclude that the SE Reports are *not* administratively complete because the following information is not included in the SE Reports. After receipt of amendments during the review process, the following is deficient with respect to administrative completeness:

- Full identification of the new and predicate tobacco products: missing tobacco cut size²

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered (GF) products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated October 30, 2015, March 2, 2016, and April 20, 2017, for SE0009624-SE0009630 and April 21, 2017, for SE0009631-SE0009632 and SE0009634-SE0009647, conclude that based on the information provided, OCE was unable to determine that the predicate tobacco products are GF.

The applicant did not provide an adequate test marketing statement; the included statement was for the general brand of the tobacco product but not for the specific predicate tobacco products listed. Additionally, the applicant's submitted evidence (1) did not provide sufficient detail to link to a specific line item on a bill of lading, invoice, or other evidence of commercial marketing to the tobacco product under review and (2) showed commercial marketing after February 15, 2007, but did not include evidence of commercial marketing other than exclusively in test markets on or before February 15, 2007. On five separate occasions, OCE requested a test market statement and specific evidence of commercial marketing in the United States as of February 15, 2007.

Although it is the applicant's burden to demonstrate that its predicate product was commercially marketed in the United States as of February 15, 2007, in addition to its multiple requests for information, OCE performed independent evidence research (IER), which analyzed eight independent criteria.³ The information provided by the applicant, as well as OCE's IER, did not show

² This identification was not required for acceptance of a provisional SE Report. Additionally, the applicant stated this was not applicable; however, FDA disagrees. In the case of dry snuff, tobacco particle size can be submitted for tobacco cut size.

³ When an applicant is not responsive to FDA's requests or does not provide enough evidence to support a finding of predicate eligibility, OCE may perform an IER to verify predicate eligibility. If OCE cannot verify evidence of commercial marketing as of February 15, 2007, the predicate tobacco product is not eligible and an NSE order issues.

that the predicate tobacco products were commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007.

Specifically:

1. The information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

Provide a statement that the predicate tobacco product was not exclusively in a test market in the United States as of February 15, 2007. Note, the statement should clearly reference the predicate tobacco product associated with your SE Report, and it should clearly mention the test marketing status of the predicate tobacco product as of February 15, 2007. In addition, this statement should be from an individual who has knowledge of the test marketing status of the predicate tobacco product and who has the authority to make such a statement.

2. The information submitted does not include evidence that demonstrates that the predicate tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.

Provide evidence that shows commercial marketing of the tobacco product in the United States as of February 15, 2007. The information submitted should demonstrate (individually or collectively) that the tobacco product(s) was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. If you cannot provide documentation specifically dated on February 15, 2007, provide documentation of commercial marketing for a reasonable period of time before and after February 15, 2007. For each piece of evidence submitted, provide a brief statement or chart that clearly identifies the link between any abbreviation, symbol, or reference used in the evidence (e.g., item number and/or product description) to the tobacco product under review.

In addition, because the new tobacco products are not substantially equivalent to the predicate tobacco products and are provisional SE Reports, OCE did not complete reviews 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).

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because OCE did *not* conclude that the predicate tobacco products were commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. As such, these SE Reports do not contain eligible predicate tobacco products⁴ to use for a comparison of characteristics in a determination of substantial equivalence.

⁴ An eligible predicate product is either a product that was commercially marketed in the United States as of February 15, 2007, or a product that has previously been found substantially equivalent and in compliance with the FD&C Act.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(b), issuance of an order finding a tobacco product not substantially equivalent (NSE) under section 910(a) of the FD&C is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or environmental impact statement (EIS). Because the action results in preventing a new product from entering the market, there are no new or different environmental impacts to consider. FDA has determined that there are no extraordinary circumstances requiring the preparation of an EA.

6. CONCLUSION AND RECOMMENDATION

The applicant has not demonstrated that the predicate tobacco product meets statutory requirements for eligibility (i.e., the predicate product was not shown to be commercially marketed in the United States as of February 15, 2007, or previously found substantially equivalent and in compliance with the Act). Therefore, scientific review was not initiated for these SE Reports.

These orders fall within a class of actions that are categorically excluded from environmental assessment. FDA concluded that categorical exclusion is warranted and no extraordinary circumstances exist which would require preparation of an environmental assessment or an environmental impact statement.

NSE order letters should be issued for the new tobacco products in SE0009624-SE0009632 and SE0009634-SE0009647, as identified on the cover page of this review.

6.1. DEFICIENCIES FOR SE0009624-SE0009632 AND SE0009634-SE0009647

The NSE order letter for SE0009624 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: blackberry) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: blackberry) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009625 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: chocolate) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: chocolate) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted

appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009626 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: seville) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: seville) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009627 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: coffee cream) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: coffee cream) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009628 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letters for SE0009629 and SE0009630 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: lemon toast) is an eligible

predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: lemon toast) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009631 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: rum & raisin) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: rum & raisin) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009632 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: brandy) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: brandy) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009634 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: strawberry and cherry) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: strawberry and cherry) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009635 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky and honey menthol) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 10 grams, characterizing flavor: whisky and honey menthol) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009636 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: apricot) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: apricot) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009637 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: raspberry) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: raspberry) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letters for SE0009638 and SE0009641 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: spearmint) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: spearmint) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the

general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009639 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: plain) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: plain) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009640 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cherry) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cherry) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009642 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: vanilla) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: vanilla) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009643 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: blueberry) is an eligible predicate

tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: blueberry) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009644 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cinnamon) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cinnamon) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009645 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: coffee) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: coffee) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009646 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cola) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: cola) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.

The NSE order letter for SE0009647 should cite the following deficiency:

1. Your SE Report does not provide information to demonstrate that Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: licorice) is an eligible predicate tobacco product. The information you provided fails to show commercial marketing (other than exclusively in test markets) of Wilsons Snuff (package type: tin, package quantity: 5 grams, characterizing flavor: licorice) as of February 15, 2007. The identification of your predicate tobacco product remains unclear. The evidence submitted appears to be for the general brand of the tobacco product and it does not appear to show commercial marketing of the specific tobacco product under review. Additionally, the information submitted does not include a sufficient statement that the predicate tobacco product was not exclusively in a test market on February 15, 2007.