

Technical Project Lead (TPL) Review: SE0000084, SE0000085, SE0000086, SE0000087, SE0005809, SE0005810, SE0005811, SE0005812, SE0005813, SE0005814, SE0005815 and SE0005817

SE0000084: Red Man 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000085: Red Man Golden Blend 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000086: Red Man Select 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000087: Red Man Silver Blend 2 oz	
Package Type	Pouch
Package Quantity	2 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005809: Red Man 3.75 oz	
Package Type	Pouch
Package Quantity	3.75 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005810: Pay Car 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural

¹ The applicant stated that "none and natural mean that it does not have a characterizing flavor."

SE0005811: Red Horse 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005812: Union Standard 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005813: Work Horse 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005814: Red Man Golden Blend 3.75 oz	
Package Type	Pouch
Package Quantity	3.75 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005815: Red Man Silver Blend 3 oz	
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005817: J.D.'s Blend 8 oz	
Package Type	Pouch
Package Quantity	8 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
Attributes of SE Reports	
Applicant	Swedish Match North America, Inc.
Report Type	Provisional
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Chewing Tobacco
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Shixia Feng -S
Date: 2019.01.30 13:09:59 -05'00'

Shixia Feng, Ph.D.
Chief, Chemistry Branch II
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)

Matthew R. Holman -S	Digitally signed by Matthew R. Holman -S Date: 2019.01.30 13:34:17 -05'00'
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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:

SE0000084: Red Man 3 oz	
Product Name	Red Man
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000085: Red Man Golden Blend 3 oz	
Product Name	Red Man Golden Blend
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000086: Red Man Select 3 oz	
Product Name	Red Man Select
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0000087: Red Man Silver Blend 2 oz	
Product Name	Red Man Silver Blend
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005809: Red Man 3.75 oz	
Product Name	Red Man
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural

SE0005810: Pay Car 3 oz	
Product Name	Pay Car
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005811: Red Horse 3 oz	
Product Name	Red Horse
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005812: Union Standard 3 oz	
Product Name	Union Standard
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005813: Work Horse 3 oz	
Product Name	Work Horse
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005814: Red Man Golden Blend 3.75 oz	
Product Name	Red Man Golden Blend
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural
SE0005815: Red Man Silver Blend 3 oz	
Product Name	Red Man Silver Blend
Package Type	Pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural

SE0005817: J.D.'s Blend 8 oz	
Product Name	J.D.'s Blend
Package Type	Pouch
Package Quantity	8 ounces
Tobacco Cut Size	(b) (4)
Characterizing Flavor ¹	Natural

The predicate tobacco products are loose chewing smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 10, 2011, FDA received twelve SE Reports from Swedish Match USA, Inc. FDA issued Acknowledgement letters to the applicant on July 19, 2011, for SE0000084-SE0000087 and on February 20, 2013, for SE0005809-SE0005815 and SE0005817. FDA issued an Advice/Information (A/I) Request letter on December 27, 2012, for SE0000084, on November 21, 2012, for SE0000085-SE0000087, and on April 10, 2013, for SE0005809-SE0005815, and SE0005817. FDA received the response to the A/I Request letters on January 25, 2013, for SE0000084 (SE0006478), on December 17, 2012, for SE0000085-SE0000087 (SE0005325-SE0005327, respectively), and on April 26, 2013, for SE0005809-SE0005815, and SE0005817 (SE0008284-SE0008290 and SE0008292, respectively). FDA received a response to the April 17, 2013, email request for predicate product information on April 23, 2013 (SE0008261). FDA issued a Notification letter on May 11, 2017, to inform the applicant that scientific review would begin on June 25, 2017. FDA received an amendment containing a request for an extension of time to respond to FDA's Notification letter on May 30, 2017 (SE0014126). FDA received an amendment containing clarification information relating to predicate Grandfathered products on June 12, 2017 (SE0014143). FDA issued an Extension Request Denied letter on June 14, 2017. FDA issued a A/I Request letter on July 2, 2018. FDA received the response to the A/I Request letter on August 31, 2018 (SE0014865). On September 13, 2018, FDA received a solicited amendment that contained a missing attachment from the August 31, 2018, A/I response (SE0014873). FDA received a response from an email request for surrogate product information on October 19, 2018 (SE0014894). FDA received a response to an information request on January 3, 2019 (SE0015401).

Product Name	SE Report	Amendments
Red Man 3 oz	SE0000084	SE0004654 SE0006478 SE0008261 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401

Product Name	SE Report	Amendments
Red Man Golden Blend 3 oz	SE0000085	SE0004654 SE0005325 SE0008261 SE0014126 SE0014143 SE0014865 SE0014873 SE0014894 SE0015401
Red Man Select 3 oz	SE0000086	SE0004654 SE0005326 SE0008261 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Red Man Silver Blend 2 oz	SE0000087	SE0004654 SE0005327 SE0008261 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Red Man 3.75 oz	SE0005809	SE0004654 SE0008261 SE0008284 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Pay Car 3 oz	SE0005810	SE0004654 SE0008261 SE0008285 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401

Product Name	SE Report	Amendments
Red Horse 3 oz	SE0005811	SE0004654 SE0008261 SE0008286 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Union Standard 3 oz	SE0005812	SE0004654 SE0008261 SE0008287 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Work Horse 3 oz	SE0005813	SE0004654 SE0008261 SE0008288 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401
Red Man Golden Blend 3.75 oz	SE0005814	SE0004654 SE0008261 SE0008289 SE0014126 SE0014143 SE0014865 SE0014873 SE0014894 SE0015401
Red Man Silver Blend 3 oz	SE0005815	SE0004654 SE0008261 SE0008290 SE0014126 SE0014143 SE0014865 SE0014873 SE0015401

Product Name	SE Report	Amendments
J.D.'s Blend 8 oz	SE0005817	SE0004654 SE0008261 SE0008292 SE0014126 SE0014143 SE0014865 SE0014873 SE0014894 SE0015401

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 Stephanie Redus on November 21, 2012, December 27, 2012, and April 10, 2013, Joanna Randazzo on February 15, 2013, and May 21, 2013, Shireen Fotelargias on September 5, 2018.

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

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered 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 June 15, 2017, December 31, 2018, January 2, 2019 and January 23, 2019 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

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 Jenna DuMond on August 15, 2017, and Margaret Schmierer on November 2, 2018.

The final chemistry review concludes 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 related to product chemistry:

- Addition of (b) (4) mg/g (b) (4) (SE0000085 and SE0005814)
- Increase of (b) (4) mg/g (17%) (b) (4) (SE0005817)
- Addition of (b) (4) mg/g (b) (4) (SE0000087 and SE0005815)
- Decreases in all HPHCs and other provided testing data (All SE Reports)

The updated tobacco blend data for the new products in SE0000085 and SE0005814 showed the addition of (b) (4) mg/g (b) (4) and the new product in SE0005817 contained more (b) (4) compared to the predicate product ((b) (4) mg/g, 17%). Higher quantities of (b) (4) may lead to higher TSNA levels. For SE0000085 and SE0005814, (b) (4) was added to balance the decrease in (b) (4). For SE0005817, (b) (4) was increased because (b) (4) was decreased, and (b) (4) was processed into rolls to resemble strips of (b) (4). The applicant claims that both (b) (4) and (b) (4) are (b) (4) and in all three cases, the new and corresponding predicate tobacco products use the same types of tobacco with same total quantities. The applicant further claims that (b) (4) and (b) (4) are not known to have different HPHC profiles. To address tobacco blend differences, the applicant provided HPHC data (acetaldehyde, crotonaldehyde, formaldehyde, arsenic, cadmium, B[a]P, nicotine, free nicotine, NNK, NNN, and ammonia) and pH in the new and corresponding predicate tobacco products. The HPHC quantities and pH are lower (up to 44% decreases) or similar in the new product compared to the corresponding predicate tobacco product. Therefore, the differences in tobacco blend do not cause the new products to raise any new questions of public health. There is an addition of (b) (4) mg/g (b) (4), a complex ingredient containing (b) (4) and (b) (4), in the new products in SE0000087 and SE0005815. This ingredient was not present in the predicate product, so this ingredient difference was deferred to toxicology for further review. Additionally, the applicant used surrogate predicate products for stability testing, in place of predicate products in SE0000085 and SE0005814. The surrogate predicate product and the predicate product have different tobacco blends, which raises concern from a chemistry perspective regarding the suitability of the surrogate predicate product for stability testing. However, evaluation of the stability data was deferred to microbiology.

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

Engineering reviews were completed by Sun Yan on August 14, 2017, and Drew Katherine on October 15, 2018.

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

tobacco products do not cause the new tobacco products to raise different questions of public health related to product engineering.

4.3. MICROBIOLOGY

Microbiology reviews were completed by David Craft on August 14, 2017, and November 1, 2018.

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

SE0000084 and SE0005809-SE0005813

- Decrease in the amount of cigar and (b) (4)
- An increase in NNN (10-16%), NNK (9-24%), and total TSNAs (8-16%)

SE0000085 and SE0005814

- Increase in cigar leaf tobacco and a reduction of (b) (4)
- A decrease in NNN (39-40%), NNK (58-67%), and total TSNAs (30-37%)

SE0000086

- A decrease in NNN (1-10%), NNK (3-6%), and total TSNAs (0-8%)

SE0000087 and SE0005815

- A decrease in NNN (1-9%), NNK (1-8%), and total TSNAs (1-7%)

SE0005817

- A decrease in NNN (19-23%), NNK (39-42%), and total TSNAs (19-21%)

For SE0000084, the new tobacco product showed higher NNN (10-16%), NNK (9-24%), and total TSNAs (8-16%) compared to the predicate tobacco product at each time point tested during product storage. However, these changes are not of concern based on the minor changes in moisture content (3-8%), water activity (a_w) (4-6%), nitrate (1-7%), nitrite (0-17%) and Total Aerobic Microbial Count (TAMC) (5-9%) of the new tobacco product as compared to the predicate tobacco product during product storage. For SE0000085, stability data from a surrogate predicate tobacco product was accepted for comparison because there were only minor changes (1-5%) in non-tobacco ingredients of microbiological concern between the predicate and surrogate tobacco product. Additionally, the surrogate tobacco product has

² The chemistry review found no change in the total amounts of cigar tobacco and (b) (4) in SE0000084 and SE0005809-SE0005813. I, the TPL, agree with the chemistry review's finding on tobacco blend for these SE Reports. However, in this case, this discrepancy does not change the microbiology review's conclusion regarding stability because such conclusion was based on testing data.

³ The chemistry reviewer found a decrease in cigar leaf tobacco and an increase in (b) (4) in SE0000085 and SE0005814. I, the TPL, agree with the chemistry reviewer's finding on tobacco blend for these SE Reports. However, in this case, this discrepancy does not change the microbiology review's conclusion regarding stability because such conclusion was based on testing data.

substantial differences in the amount of (b) (4) added compared to the predicate and the new tobacco product ((b) (4) mg/g, respectively), which could potentially result in increased TSNA formation and change the comparison of the new tobacco product to the surrogate predicate tobacco product with regard to TSNA content. Consequently, the new tobacco product showed lower NNN (39-40%), NNK (58-67%), and TSNA (30-37%) content compared to the surrogate predicate tobacco product at each time point tested during product storage. However, over 36 weeks of storage there was no change in NNN, a 9% increase in NNK, and no change in total TSNA content of the new tobacco product as compared to a 3% decrease in NNN, a 3% decrease in NNK, and a 3% decrease in total TSNA content of the surrogate predicate tobacco product. For SE0000086, the new tobacco product showed minor changes in NNN (1-10%), NNK (3-6%), and TSNA (0-8%) content compared to the predicate tobacco product at each time point tested during product storage. For SE0005815, the new tobacco product showed minor changes in NNN (1-9%), NNK (1-8%), and TSNA (1-7%) content at every time point tested during product storage. For SE0005817, stability data from a surrogate new and surrogate predicate tobacco product was accepted as the only difference between the new or predicate and corresponding surrogate tobacco products was package quantity. The surrogate new tobacco product showed lower NNN (19-23%), NNK (39-42%), and total TSNA (19-21%) content compared to the surrogate predicate tobacco product at each time point tested during product storage.

The applicant did not provide any stability testing data for the new and corresponding predicate tobacco products in SE0005809-SE0005813, SE0005814 and SE0000087. However, stability data and conclusions drawn from the data analysis for the new tobacco products in SE0000084, SE0000085 and SE0005815 can be extrapolated to the new tobacco products in SE0005809-SE0005813, SE0005814 and SE0000087, respectively based on the identical product composition between the new tobacco products in each group.

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 microbiology perspective.

4.4. TOXICOLOGY

Toxicology reviews were completed by Carmine Leggett on August 17, 2017, and Prince Awuah on October 22, 2018.

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 related to toxicology:

- Addition of (b) (4) mg/g (b) (4) (SE0000087 and SE0005815)
- 40% decrease of (b) (4) (SE0000087 and SE0005815)
- Addition or increases in (b) (4) (SE0000085, SE0005814, and SE0005817)

While (b) (4) is added to the new products in SE0000087 and SE0005815, another (b) (4) (b) (4), is decreased by 40% (b) (4) mg/g). Long-term studies in animals given (b) (4) at levels up to 15% in the diet have not shown deleterious effects, and humans with a daily intake of 40 g showed it was well tolerated. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) determined that there was no need for limiting (b) (4) as a food additive from a toxicological perspective. Additionally, the applicant indicated that there are increases of (b) (4) in the tobacco blend in SE0000085, SE0005814, and SE0005817; however, there is no change in the overall tobacco quantity in all SE Reports. Moreover, the updated HPHC data show all HPHCs tested (including ammonia, arsenic, cadmium, lead, acetaldehyde, crotonaldehyde, formaldehyde, B[a]P, NNN, and NNK) were either decreased or not changed in the new tobacco products compared to the corresponding predicate tobacco products. 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.

4.5. SOCIAL SCIENCE

Social science reviews were completed by James Henrie on December 8, 2017, and Rhonda Moore on October 17, 2018.

The final social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following differences related to social science:

- Decrease in package quantity of 33% (SE0000087)
- Increase in package quantity of 25% (SE0005809 and SE0005814)
- Increase in package quantity of 167% (SE0005817)

The social science review states that per the memo “Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products” dated December 7, 2017, such changes do not cause the new products to raise different questions of public health from a social science perspective. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary for each SE Report. FDA has determined that the health information summary provided for these SE Reports would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco products into interstate commerce.

5. ENVIRONMENTAL DECISION

Environmental review was completed by William Brenner on November 16, 2018.

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports (SE0000084-SE0000087, SE0005809-SE0005815, and SE0005817) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. In the case of these 12 SE Reports, EPA's Environmental Compliance History Online (ECHO) database listed a status of significant noncompliance under the Clean Water Act at the manufacturing facility where these products are made. FDA requested, and the applicant provided, acceptable documentation of the facility's resolution of this issue and current status of full compliance. Therefore, FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) mg/g (b) (4) (SE0000085 and SE0005814)
- Increase of (b) (4) mg/g (17%) (b) (4) (SE0005817)
- Decreases in all HPHCs and other provided testing data (All SE Reports)
- Addition of (b) (4) mg/g (b) (4) (SE0000087 and SE0005815)
- 40% decrease of (b) (4) syrup (SE0000087 and SE0005815)
- Decrease in package quantity of 33.33% (SE0000087)
- Increase of package quantity of 25% (SE0005809 and SE0005814)
- Increase of package quantity of 166.67% (SE0005817)
- Stability data:
 - An increase in NNN (10-16%), NNK (9-24%), and total TSNAs (8-16%) (SE0000084 and SE0005809-SE0005813)
 - A decrease in NNN (39-40%), NNK (58-67%), and total TSNAs (30-37%) (SE0000085 and SE0005814)
 - A decrease in NNN (1-10%), NNK (3-6%), and total TSNAs (0-8%) (SE0000086)
 - A decrease in NNN (1-9%), NNK (1-8%), and total TSNAs (1-7%) (SE0000087 and SE0005815)
 - A decrease in NNN (19-23%), NNK (39-42%), and total TSNAs (19-21%) (SE0005817)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new products in SE0000085, SE0005814, and SE0005817 contain more (b) (4) (b) (4) mg/g, respectively). However, these differences are small relative to the total amount of tobacco (less than 0.6%), which is not expected to have a large impact on the HPHC data. The HPHC testing data for all new products are either similar or lower compared to the corresponding predicate products. The new products in SE0000087 and SE0005815 have an addition of (b) (4) and a decrease in (b) (4). However, the toxicology review concludes that these changes do not raise toxicological concerns because JECFA has not specified limitations for (b) (4) and it is well tolerated at the level of

⁴ The chemistry review identified an addition of (b) (4) mg/g (b) (4) solution, while the toxicology review identified an addition of (b) (4) mg/g of (b) (4). Both values were reported by the applicant. The value identified by the toxicology review is listed here for toxicological evaluation.

inclusion. In addition, a decrease in (b) (4) is not expected to increase the toxicity. There are product package quantity changes in SE0000087, SE0005809, SE0005814, and SE0005817. However, the social science review states that such changes do not cause the new products to raise different questions of public health from a social science perspective.

Based on the data measured from the stability studies, there is no significant changes in microbial activity. For SE0000084, although the new product showed higher levels of NNN (10-16%), NNK (9-24%), and total TSNAs (8-16%) compared to the predicate product at each time point tested during storage, these changes are not of concern based on the minor changes in moisture content, aw, nitrate, nitrite and Total TAMC of the new tobacco product compared to the predicate tobacco product during product storage. For SE0000085, although the stability data from a surrogate predicate tobacco product was used for comparison, there was no change or only minor changes in NNN, NNK, and total TSNAs in the new tobacco product over 36 weeks of storage. For SE0000086 and SE0005815, the new tobacco product showed minor changes in NNN, NNK, and TSNAs compared to the predicate tobacco product at each time point tested during product storage. For SE0005817, stability data from a surrogate new and surrogate predicate tobacco product was accepted as the only difference between the new or predicate and corresponding surrogate tobacco products was package quantity. The surrogate new tobacco product showed lower NNN (19-23%), NNK (39-42%), and total TSNAs (19-21%) compared to the surrogate predicate tobacco product at each time point tested during product storage. For SE0005809-SE0005813, SE0005814, and SE0000087, stability data and conclusions drawn from the data analysis for the new tobacco products in SE0000084, SE0000085 and SE0005815 can be extrapolated to the new tobacco products in SE0005809-SE0005813, SE0005814 and SE0000087, respectively based on the identical product composition between the new tobacco products in each group. 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 products meet statutory requirements because it was determined that they are grandfathered tobacco products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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.

Because the proposed action is issuing SE orders for the provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0000084-SE0000087, SE0005809-SE0005815, and SE0005817 as identified on the cover page of this review.