Technical Project Lead (TPL) Review:

SE0003202, SE0003205, SE0003207, SE0003209, and SE0003212

SE0003202: Union Full Flavor 100's Box	
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	21.3 %
Characterizing Flavor	None
SE0003205: Union Gold 100's Box	
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	33.3%
Characterizing Flavor	None
SE0003207: Union Platinum 100's Box	
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	32.2%
Characterizing Flavor	None
SE0003209: Union Menthol 100's Box	
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	20.2 %
Characterizing Flavor	Menthol

SE0003212: Union Menthol Gold 100's Box	
Package Type	Box
Package Quantity	20 Cigarettes
Length	100mm
Diameter	7.79mm
Ventilation	32.4 %
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Heritage Tobacco, LLC
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Not Substantially Equivalent (NSE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2020.05.06 09:16:55 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy 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: 2020.05.06 09:22:36 -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:

SE0003202: Union Full Flavor 100's Box	
Product Name	Union Full Flavor 100's Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	21.3 %
Characterizing Flavor	None
SE0003205: Union Gold 100's Box	
Product Name	Union Gold 100's Box
Package Type[1]	Box and Soft Pack
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	33.3 %
Characterizing Flavor	None
SE0003207: Union Platinum 100's Box	
Product Name	Union Platinum 100's Box
Package Type[1]	Box and Soft Pack
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	32.2 %
Characterizing Flavor	None
SE0003209: Union Menthol 100's Box	
Product Name	Union Menthol 100's Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	20.2 %
Characterizing Flavor	Menthol

[1] The Office of Compliance and Enforcement reviewed two package types (hard and soft pack) for the predicate tobacco product. All other unique identification properties are identical.

SE0003212: Union Menthol Gold 100's Box	
Product Name	Union Menthol Gold 100's Box
Package Type[2]	Box
Package Quantity	20 Cigarettes
Length	100 mm
Diameter	7.79 mm
Ventilation	32.4 %
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received these five SE Reports from the American Cigarette Company (ACC) on March 22, 2011. FDA issued Acknowledgement letters on September 15, 2011. FDA issued Advice/Information Request (A/I) letters on December 13, 2012, and May 10, 2013, addressed to ACC. On February 18, 2014, a telecon was held with Heritage Tobacco LLC regarding the transfer of ownership of all STNs from ACC. On February 19, 2014, FDA received a request for a change in ownership for all ACC products (SE0010217) from Heritage Tobacco LLC. On April 11, 2014, FDA issued an A/I letter to Heritage Tobacco LLC requesting additional information on the change of ownership. On July 11, 2014, FDA issued a Transfer of Ownership acknowledgement letter for all STNs transferred from ACC. FDA issued a Notification letter on July 11, 2014, indicating scientific review was expected to begin on August 25, 2014 (b) (4) (b) (4) FDA issued a Preliminary Finding (PFind) letter on June 26, 2015. On July 10, 2015, and August 3, 2015, FDA received the applicant's responses to the PFind letter (SE0012175 and SE0012246). On September 28, 2015, FDA received an amendment in response to Office of Compliance and Enforcement's (OCE) request for information (SE0012416). FDA issued a PFind letter on May 16, 2016. On June 6 and 10, 2016, FDA received the applicant's request for extension until July 25, 2016 (SE0013411 and SE0013424), to collect information from the records of the former owner. FDA issued an Extension Denied letter on June 14, 2016. On June 16, 2016, FDA received an amendment (SE0013427) in response to the May 16, 2016, PFind letter. On June 17, 2016, FDA received a request for FDA to reconsider the denial of the June 6, 2016, extension request (TC0001564). On July 13, 2016, FDA received the applicant's second response to the May 16, 2016, PFind letter (SE0013484). On August 9, 2016, FDA received an unsolicited amendment (SE0013558) updating the July 13, 2016, amendment (SE0013484). FDA issued a PFind letter on January 10, 2017. On February 7, 2017, FDA received the applicant's response to the January 10, 2017, Pfind letter (SE0013896). On March 10, 2017, the Office of Compliance and Enforcement (OCE) concluded the reports have conflicting predicate product package type information and insufficient detail to link specific line items on the bill of lading, invoice, or other commercial marketing dates with the predicate tobacco products. On March 13, 2017, FDA

[2] The Office of Compliance and Enforcement reviewed soft pack in their final review however they were not able to determine if either the hard pack or soft pack for this predicate tobacco product were grandfathered products.

received the applicant's response to information requested by OCE (SE0013977). On April 11, 2017, FDA received an unsolicited amendment (SE0014027) clarified which STNs their previous amendment (SE0013977) applied to. On July 20, 24, 27, 28, 2017 and August 1 and 3, 2017, teleconferences were held requesting clarification of the predicate product package type information provided in the March 13, 2017, amendment (SE0013977). On August 7, 2017, FDA received the applicant's response to the requests for clarification (SE0014234). On August 22, 2017, FDA held a telecon requesting the applicant to clearly state the package type for each predicate product for SE0003205, SE0003207, and SE0003211. On September 8, 2017, FDA followed up with the applicant on the previous predicate product information request for SE0003205, SE0003207, and SE0003211.

Due to the inability to find the predicate tobacco products grandfathered based on the information provided by the applicant alone, the Office of Compliance and Enforcement (OCE) conducted Independent Evidence Research (IER),[3] which includes a review of eight independent criteria (memo finalized May 24, 2018). The evidence collected in OCE's independent review, and the information provided by the applicant failed to demonstrate that the predicate tobacco products were commercially marketed in the United States other than exclusively in test markets, as of February 15, 2007.

Product Name	SE Report	Amendments
Union Full Flavor 100's Box	SE0003202	SE0010217
Union Gold 100's Box	SE0003205	SE0010640
Union Platinum 100's Box	SE0003207	SE0012175
Union Menthol 100's Box	SE0003209	SE0012246
Union Menthol Gold 100's Box	SE0003212	SE0012416
		SE0013411
		SE0013424
		SE0013427
		SE0013484
		SE0013558
		SE0013896
		SE0013977
		SE0014027
		SE0014234

1.3. SCOPE OF REVIEW

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

[3] When an applicant is not responsive or does not provide enough evidence to support a finding of predicate eligibility, OCE performs an IER to verify predicate eligibility. If OCE cannot verify eligibility through these means, the predicate tobacco product is not eligible and an NSE order is issued.

2. REGULATORY REVIEW

Regulatory reviews were completed by Marcella White on December 13, 2012, and Ester Hatton on June 26, 2015, May 13, 2016, January 9, 2017, and June 6, 2018.

The final review concludes the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews on October 7, 2015, February 23, 2016, March 10, 2017, May 24, 2018 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 October 7, 2017, February 23, 2016, March 10, 2017, May 24, 2018, and February 14, 2020, conclude that insufficient evidence was submitted by the applicant to demonstrate that the predicate tobacco products are GF; therefore, OCE was unable to determine that the predicate tobacco products are eligible predicate tobacco products.

Because the applicant provided insufficient information in response to OCE's multiple requests for information, OCE performed independent evidence research (IER) for these predicate tobacco products. The information provided by the applicant, as well as the IER conducted by OCE, did not show that the predicate tobacco products were commercially marketed in the United States as of February 15, 2007. Specifically, in order for OCE to determine that the predicate tobacco products are grandfathered, the applicant would need to provide information to address the following:

1. SE0003202: The applicant must show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This statutory requirement can be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted by the applicant shows commercial marketing after February 15, 2007, for the predicate product listed under SE0003202. Specifically, the firm provided an invoice dated 3/19/2007 and information linking to the predicate product described as "Florida Stamped Union 100's Box Full Flavour." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007.

   However, the applicant did not submit evidence to show commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003202. The firm attempted to use evidence for a different predicate product listed under SE0003203 to prove commercial marketing on or before February 15, 2007, for the predicate product listed in SE0003202. The predicate product in SE0003203 is a "soft pack" package type whereas the predicate product in SE0003202 is a "box" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the predicate product in SE0003203 is not applicable evidence for the predicate product in SE0003202. The applicant did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the predicate product listed under

SE0003202, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by the applicant failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003202 was commercially marketed in the United States as of February 15, 2007. In order for OCE to determine that the predicate product in SE0003202 is GF, the applicant would need to submit documentation that shows that the predicate product with the "box" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

2. SE0003205: The applicant submitted two predicate products for review. The applicant must show that each predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This statutory requirement can be accomplished either by submitting evidence that each product was commercially marketed on this date, or by submitting evidence of commercial marketing for each product within a reasonable time before and after this date.

   The evidence submitted by the applicant shows commercial marketing before February 15, 2007, for the first predicate product, Union Gold 100's Box (in a soft pack) listed under SE0003205. Specifically, the firm provided an invoice dated 2/2/2007 and information linking to the predicate product described as "Florida Stamped Union 100's Soft Pack Lights." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007. However, the applicant did not submit evidence to show commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003205.

   The evidence submitted by the applicant shows commercial marketing after February 15, 2007, for the second predicate product, Union Gold 100's Box (in a hard pack) listed under SE0003205. Specifically, the firm provided an invoice dated 3/19/2007 and information linking to the predicate product described as "Florida Stamped Union 100's Box Light." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007. However, the applicant did not submit evidence to show commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003205.

   The firm attempted to use the evidence provided for each separate predicate product listed under SE0003205 to prove commercial marketing as of February 15, 2007 for both. The first predicate product is a "soft pack" package type whereas the second predicate product is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the first predicate product is not applicable evidence for the second predicate product, and oppositely, the evidence for the second predicate product is not applicable evidence for the first predicate product. The applicant did not provide any other evidence showing commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003205, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied. The applicant did not provide any other evidence showing commercial

marketing on or before February 15, 2007, for the second predicate product listed under SE0003205, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by the applicant failed to sufficiently demonstrate that the predicate tobacco products under review for SE0003205 were commercially marketed in the United States as of February 15, 2007. In order for OCE to determine that the predicate products in SE0003205 are GF, the applicant would need to submit documentation that shows that the first predicate product in SE0003205 with the "soft pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007. The applicant would need to submit documentation that shows that the second predicate product in SE0003205 with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

3. SE0003207: The applicant submitted two predicate products for review. The applicant must show that each predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This statutory requirement can be accomplished either by submitting evidence that each product was commercially marketed on this date, or by submitting evidence of commercial marketing for each product within a reasonable time before and after this date.

   The evidence submitted by the applicant shows commercial marketing before February 15, 2007, for the first predicate product, Union Platinum 100's Box (in a soft pack) listed under SE0003207. Specifically, the firm provided an invoice dated 1/31/2007 and information linking to the predicate product described as "Union 100's Soft Pack Ultra Lights." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007. However, the applicant did not submit evidence to show commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003207.

   The evidence submitted by the applicant shows commercial marketing after February 15, 2007, for the second predicate product, Union Platinum 100's Box (in a hard pack) listed under SE0003207. Specifically, the firm provided a production report dated 8/11/2010 and information linking to the predicate product described as "Union 100's Box Platinum." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007. However, the applicant did not submit evidence to show commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003207.

   The firm attempted to use the evidence provided for each separate predicate product listed under SE0003207 to prove commercial marketing as of February 15, 2007 for both. The first predicate product is a "soft pack" package type whereas the second predicate product is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the first predicate product is not applicable evidence for the second predicate product, and oppositely, the

evidence for the second predicate product is not applicable evidence for the first predicate product. The applicant did not provide any other evidence showing commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003207, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied. The applicant did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003207, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by the applicant failed to sufficiently demonstrate that the predicate tobacco products under review for SE0003207 were commercially marketed in the United States as of February 15, 2007. In order for OCE to determine that the predicate products in SE0003207 are GF, the applicant would need to submit documentation that shows that the first predicate product in SE0003207 with the "soft pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007. The applicant would need to submit documentation that shows that the second predicate product in SE0003207 with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

4. SE0003209: The applicant must show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This statutory requirement can be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted by the applicant shows commercial marketing after February 15, 2007, for the predicate product listed under SE0003209. Specifically, the firm provided an invoice dated 3/19/2007 and information linking to the predicate product described as "Florida Stamped 100's Box Menthol." The firm also provided a production report dated 8/27/2010 and information linking to the predicate product described as "Union 100's Box Menthol." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007.

   However, the applicant did not submit evidence to show commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003209. The firm attempted to use evidence for a different predicate product listed under SE0003210 to prove commercial marketing on or before February 15, 2007, for the predicate product listed in SE0003209. The predicate product in SE0003210 is a "soft box" package type whereas the predicate product in SE0003209 is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the predicate product in SE0003210 is not applicable evidence for the predicate product in SE0003209. The applicant did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the predicate product listed under

SE0003209, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by the applicant failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003209 was commercially marketed in the United States as of February 15, 2007. In order for OCE to determine that the predicate product in SE0003209 is GF, the applicant would need to submit documentation that shows that the predicate product with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

5. SE0003212: The applicant must show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This statutory requirement can be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted by the applicant shows commercial marketing before February 15, 2007, for the predicate product listed under SE0003212. Specifically, the firm provided an invoice dated 1/31/2007 and information linking to the predicate product described as "Union 100's Soft Pack Menthol Lights." The firm also provided production reports with dates between 9/25/2006 and 1/29/2007 and information linking to the predicate product described as "Union 100's Soft Pack Menthol Gold." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007.

   However, the applicant did not submit evidence to show commercial marketing on or after February 15, 2007, for the predicate product listed under SE0003212. Therefore, this part of the requirement for proving evidence of commercial marketing has not been satisfied.

   For the foregoing reasons, the information submitted by the applicant failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003212 was commercially marketed in the United States as of February 15, 2007. In order for OCE to determine that the predicate product in SE0003212 is GF, the applicant would need to submit documentation that shows that the predicate product was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007.

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 products[4] to use for a comparison of characteristics in a determination of substantial equivalence.

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 Act is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or environmental impact statement. 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

Scientific review was not initiated by the Office of Science because there was insufficient information to determine that the predicate tobacco products were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007.

Because the proposed action is issuing NSE orders, it is a class of action that is categorically excluded under 21 CFR 25.35(b). 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.

NSE order letters should be issued for the new tobacco products in SE0003202, SE0003205, SE0003207, SE0003209, and SE0003212, as identified on the cover page of this review.

6.1. DEFICIENCIES FOR SE0003202

The NSE order letter for SE0003202 should cite the following key deficiency:

1. Your SE Report does not show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This requirement could be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted shows commercial marketing after February 15, 2007, for the predicate product listed under SE0003202. Specifically, you provided an invoice dated 3/19/2007 and information linking to the predicate product described as “Florida Stamped Union 100’s Box Full Flavour.” This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007.

   However, you did not submit evidence to show commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003202. You attempted to use

[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.

evidence for a different predicate product listed under SE0003203 to prove commercial marketing on or before February 15, 2007, for the predicate product listed in SE0003202. The predicate product in SE0003203 is a "soft pack" package type whereas the predicate product in SE0003202 is a "box" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the predicate product in SE0003203 is not applicable evidence for the predicate product in SE0003202. You did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003202, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by you failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003202 was commercially marketed in the United States as of February 15, 2007. In order for FDA to determine that the predicate product in SE0003202 is GF, you would need to submit documentation that shows that the predicate product with the "box" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

6.2. DEFICIENCIES FOR SE0003205

The NSE order letter for SE0003205 should cite the following key deficiency:

1. Your SE Report provided two predicate products for review. You must show that each predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This requirement can be accomplished either by submitting evidence that each product was commercially marketed on this date, or by submitting evidence of commercial marketing for each product within a reasonable time before and after this date.

   The evidence submitted shows commercial marketing before February 15, 2007, for the first predicate product, Union Gold 100's Box (in a soft pack) listed under SE0003205. Specifically, you provided an invoice dated 2/2/2007 and information linking to the predicate product described as "Florida Stamped Union 100's Soft Pack Lights." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007. However, you did not submit evidence to show commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003205.

   The evidence submitted shows commercial marketing after February 15, 2007, for the second predicate product, Union Gold 100's Box (in a hard pack) listed under SE0003205. Specifically, you provided an invoice dated 3/19/2007 and information linking to the predicate product described as "Florida Stamped Union 100's Box Light." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007. However, you did not submit evidence to show commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003205.

You attempted to use the evidence provided for each separate predicate product listed under SE0003205 to prove commercial marketing as of February 15, 2007 for both. The first predicate product is a "soft pack" package type whereas the second predicate product is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the first predicate product is not applicable evidence for the second predicate product, and oppositely, the evidence for the second predicate product is not applicable evidence for the first predicate product. You did not provide any other evidence showing commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003205, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied. You did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003205, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by you failed to sufficiently demonstrate that the predicate tobacco products under review for SE0003205 were commercially marketed in the United States as of February 15, 2007. In order for FDA to determine that the predicate products in SE0003205 are GF, you would need to submit documentation that shows that the first predicate product in SE0003205 with the "soft pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007. You would need to submit documentation that shows that the second predicate product in SE0003205 with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

6.3. DEFICIENCIES FOR SE0003207

The NSE order letter for SE0003207 should cite the following key deficiency:

1. Your SE Report provided two predicate products for review. You must show that each predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This requirement can be accomplished either by submitting evidence that each product was commercially marketed on this date, or by submitting evidence of commercial marketing for each product within a reasonable time before and after this date.

   The evidence submitted shows commercial marketing before February 15, 2007, for the first predicate product, Union Platinum 100's Box (in a soft pack) listed under SE0003207. Specifically, you provided an invoice dated 1/31/2007 and information linking to the predicate product described as "Union 100's Soft Pack Ultra Lights." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007. However, you did not submit evidence to show commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003207.

The evidence submitted shows commercial marketing after February 15, 2007, for the second predicate product, Union Platinum 100's Box (in a hard pack) listed under SE0003207. Specifically, you provided a production report dated 8/11/2010 and information linking to the predicate product described as "Union 100's Box Platinum." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007. However, you did not submit evidence to show commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003207.

You attempted to use the evidence provided for each separate predicate product listed under SE0003207 to prove commercial marketing as of February 15, 2007 for both. The first predicate product is a "soft pack" package type whereas the second predicate product is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the first predicate product is not applicable evidence for the second predicate product, and oppositely, the evidence for the second predicate product is not applicable evidence for the first predicate product. You did not provide any other evidence showing commercial marketing on or after February 15, 2007, for the first predicate product listed under SE0003207, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied. You did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the second predicate product listed under SE0003207, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by you failed to sufficiently demonstrate that the predicate tobacco products under review for SE0003207 were commercially marketed in the United States as of February 15, 2007. In order for FDA to determine that the predicate products in SE0003207 are GF, you would need to submit documentation that shows that the first predicate product in SE0003207 with the "soft pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007. You would need to submit documentation that shows that the second predicate product in SE0003207 with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

6.4. DEFICIENCIES FOR SE0003209

The NSE order letter for SE0003209 should cite the following key deficiency:

1. Your SE Report does not show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This requirement could be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted shows commercial marketing after February 15, 2007, for the predicate product listed under SE0003209. Specifically, you provided an invoice dated

3/19/2007 and information linking to the predicate product described as "Florida Stamped 100's Box Menthol." You also provided a production report dated 8/27/2010 and information linking to the predicate product described as "Union 100's Box Menthol." This satisfies the requirement for evidence for a reasonable period of time after February 15, 2007.

However, you did not submit evidence to show commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003209. You attempted to use evidence for a different predicate product listed under SE0003210 to prove commercial marketing on or before February 15, 2007, for the predicate product listed in SE0003209. The predicate product in SE0003210 is a "soft box" package type whereas the predicate product in SE0003209 is a "hard pack" package type. The difference in package type makes them different tobacco products. Because they are different tobacco products, the evidence for the predicate product in SE0003210 is not applicable evidence for the predicate product in SE0003209. You did not provide any other evidence showing commercial marketing on or before February 15, 2007, for the predicate product listed under SE0003209, and therefore this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by you failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003209 was commercially marketed in the United States as of February 15, 2007. In order for FDA to determine that the predicate product in SE0003209 is GF, you would need to submit documentation that shows that the predicate product with the "hard pack" package type was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period before February 15, 2007, or specifically on February 15, 2007.

6.5. DEFICIENCIES FOR SE0003212

The NSE order letter for SE0003212 should cite the following key deficiency:

1. Your SE Report does not show that the predicate product was commercially marketed in the United States (other than exclusively in test markets) as of February 15, 2007. This requirement could be accomplished either by submitting evidence that the product was commercially marketed on this date, or by submitting evidence of commercial marketing for the product within a reasonable time before and after this date.

   The evidence submitted shows commercial marketing before February 15, 2007, for the predicate product listed under SE0003212. Specifically, you provided an invoice dated 1/31/2007 and information linking to the predicate product described as "Union 100's Soft Pack Menthol Lights." You also provided production reports with dates between 9/25/2006 and 1/29/2007 and information linking to the predicate product described as "Union 100's Soft Pack Menthol Gold." This satisfies the requirement for evidence for a reasonable period of time before February 15, 2007.

However, you did not submit evidence to show commercial marketing on or after February 15, 2007, for the predicate product listed under SE0003212. Therefore, this part of the requirement for proving evidence of commercial marketing has not been satisfied.

For the foregoing reasons, the information submitted by you failed to sufficiently demonstrate that the predicate tobacco product under review for SE0003212 was commercially marketed in the United States as of February 15, 2007. In order for FDA to determine that the predicate product in SE0003212 is GF, you would need to submit documentation that shows that the predicate product was commercially marketed in the United States as of February 15, 2007, with supporting documents dated either within a reasonable period after February 15, 2007, or specifically on February 15, 2007.