U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

May 08, 2020

NOT SUBSTANTIALLY EQUIVALENT

Heritage Tobacco LLC
Attention: Luis Figueredo, Attorney
8455 SW 158th Street
Palmetto Bay, FL 33157-2180

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Mr. Figueredo:

We completed our review of your SE Reports[1] and determined that the new tobacco products are not substantially equivalent to the corresponding predicate tobacco products listed in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

The following deficiencies are the basis for our determination:

1. SE0003202 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 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

[1] Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

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.

2. SE0003205 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.

3. SE0003207 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.

4. SE0003209 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.

5. SE0003212 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.

Your SE Reports lack sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that these new tobacco products are not substantially equivalent to an appropriate predicate tobacco product. Upon issuance of this order, your tobacco products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

To provide time for a sell-off of the products that are the subject of these NSE orders, FDA does not intend to take an enforcement action for at least 30 calendar days from the date of this letter. FDA does not intend to post notice of this NSE order on its misbranded and adulterated NSE Tobacco Products website unless and until it affirms the NSE orders. This compliance policy does not extend to FD&C Act requirements other than the requirement of premarket review. For more information, see https://www.fda.gov/tobacco-products/compliance-enforcement-training/manufacturing.

FDA requests that, **within 15 days** of this letter, you submit a plan detailing the steps that you plan to take to ensure that these misbranded and adulterated products are not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish these misbranded and adulterated products from legally marketed tobacco products, including, but not limited to lot numbers, manufacturing codes, and manufacturing dates. The plan should also include a list of your direct accounts and associated contact information. Submit your plan to the address below with a cover letter that includes the following text in the subject line:

COMPLIANCE PLAN for SE0003202, SE0003205, SE0003207, SE0003209, SE0003212

FDA will post product information on its misbranded and adulterated NSE Tobacco Products website, available to the public. For more information, see https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/misbranded-and-adulterated-nse-tobacco-products.

We remind you that you are required to update your listing information in June and December of each year under section 905(i)(3) of the FD&C Act. As part of this listing update, under section 905(i)(3)(B) of the FD&C Act, you must provide information on the date of discontinuance and product identity for any product you discontinue.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[2,3] using eSubmitter.[4] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[5]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Ester Hatton, Regulatory Health Project Manager, at (240) 402 - 4259 or Ester.Hatton@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2020.05.08 10:58:04 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Amendments Received for These Applications

[2] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[3] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[4] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter
[5] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Product Manufacturer:	Heritage Tobacco LLC	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product Specific Attributes	**Predicate Tobacco Product Specific Attributes**
	SE0003202: Union Full Flavor 100's Box[6]	**SE0003202: Union Full Flavor 100's Box**[6]
Date of Submission:	March 21, 2011	N/A
Date of Receipt:	March 22, 2011	N/A
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	100 mm	100 mm
Diameter:	7.79 mm	7.79 mm
Ventilation:	21.3 %	21.3 %
	SE0003205: Union Gold 100's Box[6]	**SE0003205: Union Gold 100's Box**[6,7]
Date of Submission:	March 21, 2011	N/A
Date of Receipt:	March 22, 2011	N/A
Package Type:	Box	Box and Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	100 mm	100 mm
Diameter:	7.79 mm	7.79 mm
Ventilation:	33.3 %	33.3 %
	SE0003207: Union Platinum 100's Box[6]	**SE0003207: Union Platinum 100's Box**[6,7]
Date of Submission:	March 21, 2011	N/A
Date of Receipt:	March 22, 2011	N/A
Package Type:	Box	Box and Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	100 mm	100 mm
Diameter:	7.79 mm	7.79 mm
Ventilation:	32.2 %	32.2 %

[6] Brand/sub-brand or other commercial name used in commercial distribution.

[7] Two different products provided (each with a different container closure)

	SE0003209: Union Menthol 100's Box [6]	SE0003209: Union Menthol 100's Box [6]
Date of Submission:	March 21, 2011	N/A
Date of Receipt:	March 22, 2011	N/A
Package Type:	Box	Box
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	N/A	Grandfathered
Length:	100 mm	100 mm
Diameter:	7.79 mm	7.79 mm
Ventilation:	20.2 %	20.2 %
	SE0003212: Union Menthol Gold 100's Box [6]	**SE0003212: Union Menthol Gold 100's Box [6]**
Date of Submission:	March 21, 2011	N/A
Date of Receipt:	March 22, 2011	N/A
Package Type:	Box	Box[8]
Package Quantity:	20 Cigarettes	20 Cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	N/A	Grandfathered
Length:	100 mm	100 mm
Diameter:	7.79 mm	7.79 mm
Ventilation:	32.4 %	32.4 %

[8] 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.

Appendix B

Amendments Received for These Applications

Amendments Received	
Date of Submission:	February 18, 2014
Date of Receipt:	February 19, 2014
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Other – Transfer of Ownership
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	(b) (4)
Date of Submission:	July 10, 2015
Date of Receipt:	July 10, 2015
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Response to June 26, 2015 Deficiency Letter
Date of Submission:	July 30, 2015
Date of Receipt:	August 3, 2015
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Other – Additional Items to Respond to June 26, 2015 Deficiency Letter
Date of Submission:	September 23, 2015
Date of Receipt:	September 28, 2015
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Other – Additional GF evidence
Date of Submission:	May 24, 2016
Date of Receipt:	June 6, 2016
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Other – Request for Extension to Resond to May 16, 2016 Deficiency Letter
Date of Submission:	June 15, 2016
Date of Receipt:	June 16, 2016
Reviewed:	Yes
SE Reports being amended:	All[9]
Status:	Active
Brief Description:	Response to May 16, 2016 Deficiency Letter

[9] This amendment applies to all STNs subject to this NSE order letter.

Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	July 11, 2016 July 13, 2016 Yes All[9] Active Other – Additional Information for New and Predicate Products
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	July 26, 2016 August 9, 2016 Yes All[9] Active Other – Updates to Response to May 16, 2016 Deficiency Letter
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	February 1, 2017 Febraury 7, 2017 Yes All[9] Active Response to January 10, 2017 Deficiency Letter
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	February 27, 2017 March 13, 2017 Yes All[9] Active Other – Request to make corrections to chart previously submitted on September 26, 2015
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	April 5, 2017 April 11, 2017 Yes All[9] Active Other – Clarificaiton of items in February 27, 2017 submission
Date of Submission: **Date of Receipt:** **Reviewed:** **SE Reports being amended:** **Status:** **Brief Description:**	August 2, 2017 August 7, 2017 Yes All[9] Active Other – Additional information for predicate products