



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

October 18, 2019

SUBSTANTIALLY EQUIVALENT

ITG Brands, LLC
ATTENTION: Carole Folmar, J.D., Director of Regulatory & Scientific Affairs
714 Green Valley Road
Greensboro, NC 27408

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

Dear Ms. Folmar:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A. Under the provisions of sections 910 and 905(j) of the FD&C Act, you may continue to legally market the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make publicly available our finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

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

If you have any questions, please contact Megan Nguyen, Regulatory Health Project Manager, at (301) 796 - 7826 or Megan.Nguyen@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2019.10.18 09:36:28 -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 – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Product Manufacturer:	ITG Brands, LLC	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number:	SE0000004	GF1501240
Date of Submission:	August 31, 2010	N/A
Date of Receipt:	September 1, 2010	N/A
Product Name:²	Winston Red Box	Winston Full Flavor Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	83 mm	83 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	17 %	17 %
Submission Tracking Number:	SE0000005	GF1501296
Date of Submission:	November 5, 2010	N/A
Date of Receipt:	November 5, 2010	N/A
Product Name:²	Winston White Box	Winston Ultra Light Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	83 mm	83 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	54 %	54 %
Submission Tracking Number:	SE0000006	GF1501108
Date of Submission:	November 5, 2010	N/A
Date of Receipt:	November 5, 2010	N/A
Product Name:²	Winston White 100's Box	Winston Ultra Light 100s Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	98 mm	98 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	60 %	60 %

² Brand/sub-brand or other commercial name used in commercial distribution.

³ The applicant submitted the circumference which allowed for a calculation of diameter.

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number:	SE0000007	GF1501106
Date of Submission:	November 5, 2010	N/A
Date of Receipt:	November 5, 2010	N/A
Product Name:²	Winston Red 100's Box	Winston Full Flavor 100s Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	98 mm	98 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	17 %	17 %
Submission Tracking Number:	SE0000008	GF1501241
Date of Submission:	November 5, 2010	N/A
Date of Receipt:	November 5, 2010	N/A
Product Name:²	Winston Gold Box	Winston Light Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	83 mm	83 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	32 %	32 %
Submission Tracking Number:	SE0000009	GF1501107
Date of Submission:	November 5, 2010	N/A
Date of Receipt:	November 5, 2010	N/A
Product Name:²	Winston Gold 100's Box	Winston Light 100s Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered
Length:	98 mm	98 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	28 %	28 %

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number:	SE0000069	GF1501100
Date of Submission:	Decmeber 23, 2010	N/A
Date of Receipt:	December 28, 2010	N/A
Product Name:²	Salem 100's Box	Salem Full Flavor Green Label 100s Box
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	Menthol	Menthol
Eligibility Status:	N/A	Grandfathered
Length:	98 mm	98 mm
Diameter:³	7.79 mm	7.79 mm
Ventilation:	17 %	17 %

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

Description of the new tobacco products

Description of the predicate tobacco products

List of all differences in characteristics between the new and predicate tobacco products

Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health

Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.