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

July 08, 2019

NOT 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, Refer to Appendix A

Dear Ms. Folmar

The Food and Drug Administration (FDA) completed review of your Reports Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Reports), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your SE Reports, we find the new tobacco products are not substantially equivalent to the corresponding eligible predicate tobacco products specified in Appendix A.

We have described below our basis for this determination.

1. SE0002149, SE0002152, SE00002154, and SE0002156 contained information regarding the TNCO/HPHC analysis and results, and Quantitative Risk Analysis (QRA) to address ingredient changes and increases in HPHC yields produced by the new product compared to the corresponding 2016 remanufactured predicate product. You provided HPHC information to demonstrate that differences in tobacco grade/blend and non-tobacco ingredients do not cause the new products to raise different questions of public health. However, analysis of the HPHC yields provided has determined that many carcinogenic and/or toxic HPHCs were significantly elevated and not analytically equivalent in the new products compared to the corresponding 2016 remanufactured predicate products under the ISO and/or HCI smoke regimens:

    a. SE0002149 – 12% increase in HCI regimen smoke yields of carbon monoxide
    b. SE0002152 – Increases in ISO smoke regimen yields of acrolein (19%), crotonaldehyde (30%), and formaldehyde (22%)
    c. SE0002154 – Increases in ISO smoke regimen yields of acetaldehyde (41%), acetone (43%), acrolein (33%), acrylonitrile (41%), 4-aminobiphenyl (32%), benzene (33%), benzo-α-pyrene (30%), carbon monoxide (40%), crotonaldehyde (30%), NNK (32%), and toluene (45%); increases in HCI smoke regimen yields of carbon monoxide (14%) and toluene (21%)
    d. SE0002156 – 22% increase in HCI regimen smoke yields of acrylonitrile

    Acetaldehyde is a nasopharyngeal and laryngeal carcinogen, as well as a respiratory tract toxicant often associated with chronic obstructive pulmonary diseases (COPD), and

a cardiovascular and reproductive/developmental toxicant. Acetone is a respiratory toxicant. Acrolein is an upper respiratory tract toxicant associated with COPD as well as a cardiovascular and reproductive/developmental toxicant. Acrylonitrile is a respiratory and bladder carcinogen and a cardiovascular and respiratory toxicant. 4-Aminobiphenyl is a liver and bladder carcinogen. Benzene causes acute myeloid leukemia and other cancers of blood-forming organs, and is a cardiovascular and a reproductive/developmental toxicant. Benzo-α-pyrene is a lung carcinogen as well as a cardiovascular toxicant and a reproductive/developmental toxicant. Carbon monoxide is both a cardiovascular and a reproductive/developmental toxicant, and is associated with adverse neurobehavioral/cognitive changes. Crotonaldehyde is a respiratory and liver carcinogen as well as both a respiratory and a cardiovascular toxicant. Formaldehyde is an upper respiratory carcinogen, and both a respiratory and a cardiovascular toxicant. NNK is a respiratory carcinogen. Lastly, toluene is an upper respiratory and reproductive/developmental toxicant.

You voluntarily submitted quantitative risk assessments (QRAs) to support your view that increases in HPHC levels as a result of tobacco blend and non-tobacco ingredient changes do not cause the new product to raise different questions of public health. However, the evidence you submitted does not support similarity of cancer risk and non-cancer hazard between the new and predicate products because there are no analytically non-equivalent decreases in HPHCs that have the same critical effect, molecular target, biochemical mechanism of action, magnitudinal yield change, and/or potency/toxicity that may offset HPHC increases between new and predicate products. Thus, a risk assessment approach whether quantitative, semi-quantitative, or qualitative is unlikely to demonstrate that the new products for SE0002149, SE0002152, SE0002154, and SE0002156 do not raise different questions of public health.

Therefore, you needed to provide new scientific evidence and a rationale that the HPHC increases associated with tobacco blend and ingredient changes in the SE Reports listed above do not cause the new products to raise different questions of public health. For example, you could provide peer-reviewed research articles, experimental data, and/or other scientifically robust sources of information relevant to the new and predicate products showing that increases in the yields of these HPHCs will not cause the new products to raise different questions of public health.

2. All of your SE Reports include data comparing the quantities of HPHCs in the new and remanufactured predicate products. Your SE Reports also include complete data sets of HPHC testing; and the mean, standard deviation and number of replicates. This is sufficient information to only statistically evaluate the reported HPHC quantities and the relative differences between the new and corresponding remanufactured predicate products. However, your SE Reports lack information necessary to fully evaluate the HPHC testing. For example, you provided only the storage conditions for TNCO and menthol/moisture, but did not provide the storage conditions for the other HPHC testing. Storage conditions may affect HPHC yields. Additionally, the analytical methods used, testing laboratory information and accreditation during the sample testing period of 2016, and reference product information was also not provided. This information is necessary to ensure accuracy, precision, quantitation limit, and specificity of the methods and assess the reliability of the reported HPHC quantities. Reference products help ensure the confidence in the testing. Without this information, a complete

evaluation of the reported results is not possible and is needed for making a favorable determination on substantial equivalence. You needed to provide the following information about HPHC testing for all the SE Reports so that we could have fully evaluated the HPHC data:

a. Reference product datasets (e.g., 1R6F)
b. Quantitative test protocols and method used
c. Testing laboratory and their accreditation(s) during the sample testing period of 2016
d. Storage conditions prior to initiating testing except for TNCO

You did not provide 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 is the subject of this NSE order, FDA does not intend to take an enforcement action for at least 30 calendar days from the date of this order. Additionally, if you appeal this decision via a request for supervisory review pursuant to 21 C.F.R. § 10.75 and FDA receives your request within 30 calendar days of this order, FDA does not intend to take an enforcement action during the pendency of the appeal review. 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 order.[1]

If you choose not to appeal this NSE order, FDA requests that within 15 days of this letter you submit a plan detailing the steps 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 contain their 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 SE0002149, SE0002152, SE0002154-SE0002156, and SE0002158

FDA will post product identifying information on its misbranded and adulterated NSE Tobacco Products website, available to the public at 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.

[1] This compliance policy does not extend to FD&C Act requirements other than the requirement of premarket review.

If you wish to appeal this decision, you can request supervisory review of this decision under 21 CFR 10.75 and submit the request 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 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.

We ask that your request be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0002149, SE0002152, SE0002154-SE0002156, and SE0002158.** In addition, we ask you to identify each basis for the request and include all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your SE Reports.

To legally market the new products described in this application, they must comply with the requirements in section 910(a)(2)(A) of the FD&C Act unless the products are subject to FDA's compliance policy as described in the guidances available at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance.

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: 2019.07.08 13:04:48 -04'00'

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

Enclosure:

Appendix A- List of New Tobacco Products Subject of This Letter

[2] For more information about CTP Portal, see: https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal

[3] The 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] See https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A

List of new tobacco products that FDA has determined are not substantially equivalent when compared to its predicate tobacco product.

Common Attributes of SE Reports	
Date of Submission:	March 22, 2011
Date of Receipt:	March 22, 2011
Product Manufacturer:	ITG Brands, LLC
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002149
Product Name:[6]	Maverick Gold Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[7]	7.88 mm
Ventilation:	45%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Maverick Lights Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Eligibility Status:	Grandfathered
Length:	99 mm
Diameter:[7]	7.89 mm
Ventilation:	34%

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

[7] The applicant submitted the circumference which allowed for a calculation of diameter.

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002152
Product Name:[6]	Maverick Menthol Gold Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:[7]	7.88 mm
Ventilation:	44%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Maverick Menthol Lights Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Eligibility Status:	Grandfathered
Length:	99 mm
Diameter:[7]	7.89 mm
Ventilation:	35%

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002154
Product Name:[6]	Maverick Silver Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[7]	7.88 mm
Ventilation:	58%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Kent III Ultra Lights 100s
Package Type:	Soft Pack
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Eligibility Status:	Grandfathered
Length:	99 mm
Diameter:[7]	7.89 mm
Ventilation:	55%

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002155
Product Name:[6]	Maverick Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	80 mm
Diameter:[7]	7.88 mm
Ventilation:	17%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Maverick [Full Flavor] Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Eligibility Status:	Grandfathered
Length:	80 mm
Diameter:[7]	7.89 mm
Ventilation:	0%

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002156
Product Name:[6]	Maverick Gold Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	80 mm
Diameter:[7]	7.88 mm
Ventilation:	40%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Maverick Lights Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Eligibility Status:	Grandfathered
Length:	80 mm
Diameter:[7]	7.89 mm
Ventilation:	30%

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0002158
Product Name:[6]	Maverick Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	99 mm
Diameter:[7]	7.88 mm
Ventilation:	22%
Predicate Tobacco Product Specific Attributes	
Product Name:[6]	Maverick [Full Flavor] Box 100s
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Eligibility Status:	Grandfathered
Length:	99 mm
Diameter:[7]	7.89 mm
Ventilation:	8%