DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 14, 2016

NOT SUBSTANTIALLY EQUIVALENT

ITG Brands, LLC
Attention: Carole B. Folmar
Director, Regulatory Affairs and Associate General Counsel
714 Green Valley Road
Greensboro, NC 27408

FDA Submission Tracking Number (STN): SE0002153

Dear Ms. Folmar,

We have completed our review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	ITG Brands, LLC
Tobacco Product Name[1]:	Maverick Menthol Silver Box 100s
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Box
Package Quantity:	20 cigarettes per box
Characterizing Flavor:	Menthol
Length:	99 mm
Diameter:	7.89 mm
Filter Ventilation:	58%

We have completed the review of your SE Report and have determined that it does not establish that the new tobacco product specified is substantially equivalent to the following predicate tobacco product:

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

Predicate Tobacco Product

Tobacco Product Manufacturer:	ITG Brands, LLC
Tobacco Product Name[2]:	Kent III Ultra Lights 100s
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 cigarettes per pack
Characterizing Flavor:	None
Length:	99 mm
Diameter:	7.89 mm
Filter Ventilation:	55%

We have described below our basis for this determination.

The following deficiency demonstrates that the new tobacco product is not substantially equivalent to the predicate tobacco product:

1. Your SE Report indicates that the new tobacco product is mentholated but the predicate tobacco product is not. You claim that the addition of menthol does not cause the new tobacco product to raise different questions of public health. However, the addition of menthol may impact the flavor and sensory effects of the new tobacco product and affect use behavior. The addition of menthol causes the new tobacco product to raise different questions of public health because menthol likely impacts initiation behaviors and progression to regular tobacco use by increasing palatability and abuse liability, increasing levels/severity of dependence, and reducing the likelihood of cessation.

Because of this deficiency, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product.

In addition, we note the following deficiencies in the information you submitted, which prevent a determination that the new tobacco product is substantially equivalent to the predicate tobacco product:

2. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report does not include ingredients in the following components of the new and predicate tobacco products:

    a. Cigarette paper
    b. Tipping paper
    c. Plug wrap

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

d. Monogram ink

In addition, your SE Report does not include information needed to uniquely identify tobacco (e.g., tobacco grading system) and non-tobacco ingredients (e.g., CAS #, grade/purity, function). The function of (b) (4) needs clarification, as your SE Report lists the function of this ingredient as both a (b) (4) . If differences exist between the composition of the new and predicate tobacco products, scientific discussion for why the differences do not cause the new tobacco product to raise different questions of public health would be needed.

3. Your SE Report provides information on the tobacco blend of the new and predicate tobacco products. Your SE Report lists (b) (4) as an ingredient in the tobacco blend in Section 7.3.1. However, no (b) (4) is reported in the ingredient table in Table 7.3.a. Therefore, clarification is needed on whether (b) (4) is included in the new and predicate tobacco products. If (b) (4) is present, the quantity (in mg/cig) is needed along with information needed to uniquely identify (b) (4) in the new and predicate tobacco products.

4. Your SE Report provides information on the ink used in the new and predicate tobacco products and states that different ink is used in the new and predicate tobacco products. However, no information is provided regarding the ingredients of the monogram ink used in the new and predicate tobacco products. In addition, Table 7.3.b lists the same ink in the new and predicate tobacco products, which seems to contradict the statement made in the SE Report that a different ink is used. Therefore, clarification on the identity of the monogram ink used in the new and predicate tobacco products is needed.

5. Your SE Report lacks adequate information on the composition of the complex ingredients. Distinguish between complex ingredients made to your specifications and those that are not. For all complex ingredients made to your specifications, your SE Report needs to list the names, functions, and quantities of the single ingredients that comprise the complex ingredients.

6. Your SE Report identifies flavor differences between the new and predicate tobacco products. For example, (b) (4) is listed in the new tobacco product, whereas (b) (4) flavor is listed in the predicate tobacco product. Such differences may impact smoke chemistry, as sugars are known to increase the mainstream smoke yields of certain carbonyls and hydrocarbons, such as formaldehyde. In addition, sugars and other flavors are used in tobacco products to mitigate the harshness of cigarette smoke and to enhance product appeal. Scientific evidence as to why such differences do not cause the new tobacco product to raise different questions of public health is needed.

7. Your SE Report indicates significant differences in the tobacco blends of the new and predicate tobacco products. The new tobacco product contains (b) (4) than the predicate tobacco product. The (b) (4) . In

addition, (b) (4) is present in the new tobacco product but not the predicate tobacco product. (b) (4) has been shown to (b) (4) There are also flavor differences between the new and predicate tobacco products, including higher amounts of (b) (4) and sugars. Pyrolysis of (b) (4) can result in the formation of phenol and formaldehyde, while pyrolysis of sugars can result in the formation of certain carbonyls and hydrocarbons, such as formaldehyde and acetone. Scientific rationale and evidence to address why these differences do not cause the new tobacco product to raise different questions of public health. One way to provide such evidence is to measure mainstream smoke yields of the following HPHCs in the new and predicate tobacco products under the Canadian Intense smoking regimen:

a. Tar
b. Carbon monoxide
c. Nicotine

Such evidence could include measurement of mainstream smoke yields of the following HPHCs in the predicate tobacco products under the ISO smoking regimen:

d. Acetone
e. Ammonia
f. Formaldehyde
g. NNN
h. NNK

8. Your SE Report provides information on the design parameters for the new and predicate tobacco products. You include the target specifications and upper and lower range limits for some but not all of the design parameters. Target specifications for all of the following design parameters for the new and predicate tobacco products are not provided and are needed to adequately characterize the products:

   a. Cigarette draw resistance (mm H_2O)
   b. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]

   In addition, the upper and lower range limits for all of the following design parameters for the new and predicate tobacco products are not provided and are needed to adequately characterize the products:

   c. Cigarette circumference (mm) (predicate tobacco product only)
   d. Cigarette draw resistance (mm H2O)
   e. Cigarette paper base paper basis weight (g/m^2)
   f. Cigarette paper base paper porosity (CU)
   g. Cigarette paper band porosity (CU) (new tobacco product)
   h. Cigarette paper band width (mm) (new tobacco product)
   i. Cigarette paper band space (mm) (new tobacco product)
   j. Filter efficiency (%) [If no filter efficiency data is available for the products,

include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]

If differences in target specifications or range limits exist between the new and predicate tobacco products, scientific evidence and discussion would be needed to demonstrate why the differences do not cause the new tobacco product to raise different questions of public health.

9. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all of the following design parameters for the new and predicate tobacco products are not provided and are needed to adequately characterize the products:

    a. Cigarette draw resistance (mm H_2O)
    b. Tobacco filler mass (mg)
    c. Cigarette paper base paper basis weight (g/m^2)
    d. Cigarette paper base paper porosity (CU)
    e. Cigarette paper band porosity (CU) (new tobacco product only)

    Certificates of analysis from the material supplier may satisfy this deficiency.

10. Your SE Report indicates differences in design parameters that need additional information in order to adequately characterize the products. The target specifications for (b) (4) from the predicate to new tobacco product. Your SE Report provides a limited rationale for these differences without a discussion of the impact on public health. An (b) (4) Therefore, scientific evidence and discussion of why the (b) (4) differences do not cause the new tobacco product to raise different questions of public health is needed.

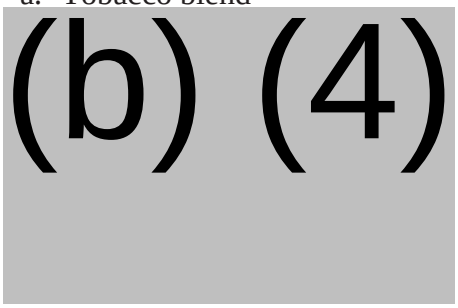
11. Your SE Report includes design parameter specifications but does not include all of the necessary data confirming that specifications are met. Your SE Report provides filter efficiency calculated from smoke analysis. However, test data is a factor in characterizing the product and is used to evaluate if specifications are met; therefore, test data needs to be based on actual results and not theoretical values. Additionally, without submitting criteria to verify the data against, the test data is of limited utility.

12. Your SE Report provides test data for design parameters that do not fall within your upper and lower range limits for the new and predicate tobacco products, indicating the specifications are not met. Therefore, confirmation of the range limits is needed along with justification for the discrepancies:

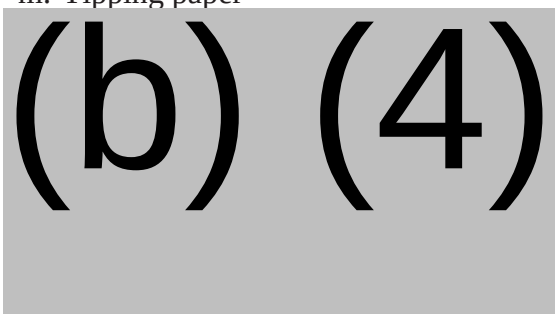
    a. Tobacco oven volatiles (predicate tobacco product only)
    b. Filter pressure drop
    c. Filter ventilation

13. Your SE Report indicates that the new tobacco product contains ingredients that can form HPHCs during pyrolysis, while the predicate tobacco product does not contain these ingredients. In addition, your SE Report does not provide the quantities of these ingredients in the predicate tobacco product. Ingredient information, including components, sub-components, and single ingredients comprising complex ingredients, is needed for the following ingredients in the new and predicate tobacco products:

    a. Tobacco blend

    j. Cigarette paper
    k. Ink
    l. Plug wrap
    m. Tipping paper

    Scientific evidence and discussion is needed to demonstrate that differences in ingredients between new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health, addressing the impact of these differences on smoke toxicity.

14. Your SE Report includes information on changes in sweeteners and other flavors in the new tobacco product. You claim that the differences in sweeteners and other flavors do not cause the new tobacco product to raise different questions of public health. However, the addition and increased amounts of sweeteners and flavors/flavor enhancers may impact the tobacco flavor of the new tobacco product and affect use behaviors. The sweeteners and flavors in the new tobacco product may be attractive to youth and inexperienced users and impact initiation behaviors and progression to regular tobacco use by increasing palatability and abuse liability. However, your SE Report does not provide scientific data and rationale demonstrating that the changes in sweeteners do not cause the new tobacco product to raise different questions of public health. Such evidence could include properly-designed taste panels comparing the new and predicate tobacco products or a clinical abuse liability assessment comparing the new and

predicate tobacco products.

Upon issuance of this order, your tobacco product is misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Therefore, you must immediately stop all distribution, importation, sale, marketing, and promotion of your tobacco product in the United States. 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.

FDA requests that within 15 days of this letter you submit a plan detailing the steps you plan to take to ensure that this misbranded and adulterated product is not further distributed, imported, sold, marketed, or promoted in the United States by others. Your plan should include information sufficient to distinguish this misbranded and adulterated product 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 SE0002153

FDA will post product identifying information on a list of tobacco products that are adulterated and misbranded due to an NSE order, available to the public at http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm#2

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.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the FDA Electronic Submission Gateway (www.fda.gov/esg) using eSubmitter, or mail to:

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

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW for SE0002153.** In addition, we request that your package identify each basis for the request and contain 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 Report.

Therefore, you must immediately stop all distribution, importation, sale, marketing, and

promotion of your tobacco product in the United States. 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.

You may not legally market the new tobacco product described in this SE Report unless (1) FDA issues an order finding the product to be exempt from the requirements of substantial equivalence and you make the required submission under section 905(j)(1)(A)(ii) of the FD&C Act, (2) FDA issues an order finding the product substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act), OR (3) FDA issues an order authorizing introduction or delivery for introduction into interstate commerce under a premarket tobacco application (section 910(c)(1)(A) of the FD&C Act).

See the following website for additional information on these three pathways: http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/default.htm.

If you have any questions, please contact Ebony Jackson, Regulatory Health Project Manager, at (240) 402 - 4499.

Sincerely,

Digitally signed by David Ashley -S
Date: 2016.07.14 12:59:50 -04'00'

David L. Ashley, Ph.D.
RADM (Ret), U.S. Public Health Service
Director, Office of Science
Center for Tobacco Products