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

October 05, 2018

NOT SUBSTANTIALLY EQUIVALENT

Skookum Creek Tobacco Company
ATTENTION: Nathan Schreiner, Attorney
Squaxin Island Legal Department
3711 SE Old Olympic Highway
Shelton, WA 98584

FDA Submission Tracking Number (STN): SE0003305

Dear Mr. Schreiner:

The Food and Drug Administration (FDA) completed 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

Date of Submission:	March 21, 2011
Date of Receipt:	March 22, 2011
Product Manufacturer:	Skookum Creek Tobacco Company
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Product Name:[1]	Traditions, 100's, "Ultra High Air"
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:[2]	7.8 mm
Ventilation:	30%
Characterizing flavor:	None

Based on our review of your SE Report, we find the new tobacco product specified above is not substantially equivalent to the following predicate tobacco product:

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] The applicant submitted the circumference which allowed for a calculation of diameter

Predicate Tobacco Product

Product Manufacturer:	Skookum Creek Tobacco Company
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
Product Name:[1]	Complete, 100's "Ultra High Air"
Package Type:	Hard Pack
Package Quantity:	20 cigarettes
Length:	99 mm
Diameter:[2]	7.8 mm
Ventilation:	30%
Characterizing flavor:	None
Eligibility Type:	Grandfathered

We have described below our basis for this determination.

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report provides contradictory tobacco blend information and does not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new tobacco products. Your SE Report includes tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of (b) (4) tobacco in the new and predicate tobacco products but does not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, your SE Report lacks the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the (b) (4) tobacco sheets. FDA needs this information to determine whether the new and predicate tobacco products have differences in the tobacco ingredients. FDA needs any other information you may have that uniquely identifies the tobacco composition used in the predicate and new tobacco products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the predicate and new products. Similarly, other ingredients are reported as "less than" ("<") results. It would be helpful to know the grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients. Examples include the following complex ingredients:

   (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
   e. All adhesive glues

   Your SE Report does not provide a detailed list including:

   a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
   b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
   c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate product

d. A justification for reporting "less than" quantities

If a difference exists between the new and predicate products, scientific evidence and rationale for why the difference does not cause the new product to raise different questions of public health would be needed. For example, if there are increases in (b) (4) [redacted] tobaccos, one way to show that the tobacco blend changes do not cause the new tobacco products to raise different questions of public health would be to provide HPHC (nicotine, CO, B[a]P, NNN, and NNK) and tar yields under both the ISO and Canadian Intense regimens and provide a rationale for why any differences in HPHC and tar yields do not cause the new products to raise different questions of public health.

2. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products includes the target specifications and range limits for the design parameters listed below. Noted parameters also require test data:

    a. Overall Cigarette Length (range limit only)
    b. Overall Cigarette Puff Count (test data only)
    c. Overall Cigarette Draw Resistance (range limits and test data only)
    d. Tobacco Filler Mass (test data only)
    e. Tobacco Moisture (test data only)
    f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
    g. Cigarette Paper Porosity (test data only)
    h. Cigarette Paper Band Porosity (test data only)
    i. Cigarette Paper Band Width (range limits only)
    j. Cigarette Paper Band Space (range limits only)
    k. Filter Efficiency (target specifications, range limits, and test data)
        1. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
    l. Filter Pressure Drop (test data only)
    m. Filter Length (range limits only)
    n. Filter Ventilation (range limits and test data only)
    o. Tipping Paper Length (range limits only)

    If like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one way to satisfy this deficiency would be to provide a Listing of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

You did not provide sufficient information to support a finding of substantial equivalence; therefore, we are issuing an order finding that this new tobacco product is not substantially equivalent to an appropriate predicate tobacco product. 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. 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.

Additionally, 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 SE0003305

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 https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm371765.htm

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 CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter), or mail it 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; if the upload is successful, submissions are considered received by DCC on the day of 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 (see http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); 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.

[3] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

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 SE0003305.** 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 Report.

To legally market the new product described in this application, it must comply with the requirements in section 910(a)(2)(A) of the FD&C Act.

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

If you have any questions, please contact Barbara Banchero, Regulatory Health Project Manager, at (301) 796-1937 or Barbara.Banchero@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.10.05 12:15:26 -04'00'

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