DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

October 05, 2015

NOT SUBSTANTIALLY EQUIVALENT

LIT Distributor, Inc.
Attention: Barry M. Boren, Attorney
One Datran 9100 South Dadeland Boulevard Suite 402
Miami, FL 33156

FDA Submission Tracking Number (STN): SE0010227

Dear Mr. Boren:

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:	LIT Distributor Inc.
Tobacco Product Name[1]:	New Dark Green King Size Box
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Not provided
Package Type:	Box
Package Quantity:	Not provided
Length:	Not provided
Diameter:	Not provided
Filter Ventilation:	Not provided
Characterizing Flavor:	Not provided

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:	Not provided
Tobacco Product Name[2]:	Not provided
Tobacco Product Category:	Not provided
Tobacco Product Sub-Category:	Not provided
Package Type:	Not provided
Package Quantity:	Not provided
Length:	Not provided
Diameter:	Not provided
Filter Ventilation:	Not provided
Characterizing Flavor:	Not provided

Your SE Report included a predicate product which you indicate was commercially marketed in the United States as of February 15, 2007. As you did not provide information to uniquely identify this predicate product a grandfather determination could not be initiated. In a future submission if you choose to use a predicate that was commercially marketed in the United States as of February 15, 2007 that has not yet been found to have grandfather status by FDA, evidence must be submitted to support this assertion.

We have described below our basis for this determination.

1. Your SE Report for the **new tobacco product** lacks information to uniquely identify the tobacco product. Multiple products for the new tobacco product could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate tobacco product you are comparing to the new tobacco product is substantially equivalent. Your SE Report only contains identification of the product name, category, subcategory, and package type for the new tobacco product. For unique identification, *all* of the following information is needed:

    a. Product subcategory
    b. Package quantity (e.g., 20 per pack)
    c. Product length (e.g., 89 mm, 100 mm)
    d. Product diameter (e.g., 6.7 mm, 8.1 mm)
    e. Ventilation (e.g., none, 10%, 25%)
    f. Characterizing flavor (e.g., none, tobacco, menthol)
    g. Additional descriptor (e.g., none, blue, single wide)

2. Your SE Report for the **predicate tobacco product** lacks information to uniquely identify the tobacco product. Multiple products for the predicate tobacco product

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

could exist due to differences in package quantity, length, width, characterizing flavor, or additional descriptors; thus, it is unclear whether the predicate tobacco product you are comparing to the new tobacco product is substantially equivalent. Your SE Reports contain information on the names of the new and predicate tobacco products, however it is not clear which tobacco products are the predicate tobacco products of each of the new tobacco products. For unique identification, *all* of the following information is needed:

a. Product name
b. Product category
c. Product subcategory
d. Package type
e. Package quantity (e.g., 20 per pack)
f. Product length (e.g., 89 mm, 100 mm)
g. Product diameter (e.g., 6.7 mm, 8.1 mm)
h. Ventilation (e.g., none, 10%, 25%)
i. Characterizing flavor (e.g., none, tobacco, menthol)
j. Additional descriptor (e.g., none, blue, single wide)

3. Your SE Report lacks information about the tobacco blends and sufficient detail to fully characterize the tobacco blend composition of the predicate and new tobacco products. We need any other information you may have that uniquely identifies the tobacco 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 tobacco products. *All* of the following information about the tobacco blends is needed for the new and predicate tobacco products:

   a. All tobacco types used to manufacture the products
   b. Quantities of all tobacco types expressed in unit of measure, such as mass per cigarette
   c. Uniquely identify information for all tobacco (e.g., tobacco grading system)

   Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry, which have been shown to affect HPHC quantities. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

4. Your SE Report lacks ingredients added to tobacco in the predicate and new tobacco products. Furthermore, your SE Reports do not include ingredients in all components and subcomponents of the predicate and new tobacco products. Without this information, we cannot determine whether the predicate and new products are substantially equivalent. A detailed list of ingredient information including *all* of the following information is needed for the new and predicate tobacco products:

a. All ingredients used to manufacture the products, include individual ingredients in complex ingredients
b. Quantities of all ingredients expressed in unit of measure, such as mass per cigarette
c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, function)

If there are any differences in composition between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

5. Your SE Report lacks HPHC data for the new and predicate tobacco products. HPHC data can provide useful evidence to demonstrate that the difference in product composition between the new and predicate products do not cause the new tobacco product to raise different questions of public health. Because it is unclear what, if any, differences exist between the new and corresponding predicate products, it is unclear what HPHC data would be useful. However, if there are differences in product characteristics likely to affect HPHC quantities, then applicable HPHC data would be needed. For smoke analysis, the measurement of HPHC yields under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. Full test data including the followings would be needed for all testing performed:

    a. Quantitative test protocols and method used
    b. Testing laboratory and their accreditation(s)
    c. Length of time between date(s) of manufacture and date(s) of testing
    d. National/international standards used and any deviations(s) from those standards. If deviation(s) is not the same for methods used for the new and predicate products, provide scientific evidence demonstrating that the testing result for the new and predicate products are accurate and comparable
    e. Number of replicates
    f. Standard deviations
    g. Complete data sets
    h. A summary of the results for all testing performed
    i. Storage conditions prior to initiating testing

6. Your SE Report does not include all of the design parameters necessary to fully characterize the predicate and new tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. **Target specifications and upper and lower range limits** are needed for *all* of the following design parameters for the predicate and new tobacco products:

    a. Cigarette length (mm)
    b. Cigarette circumference (mm)

c. Cigarette draw resistance (mm H_2O)
d. Tobacco filler mass (mg)
e. Tobacco rod density (g/cm^3)
f. Tobacco oven volatiles (OV) (%)
g. Filter ventilation (%)
h. Tipping paper length (mm)
i. Cigarette paper base paper basis weight (g/m^2)
j. Cigarette paper base paper porosity (CU)
k. Cigarette paper band porosity (CU)
l. Cigarette paper band width (mm)
m. Cigarette paper band space (mm)
n. 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)]
o. Filter length (mm)
p. Filter pressure drop (mm H_2O)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

If a difference exists between the new and corresponding predicate products, provide a rationale for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.

7. Your SE Report does not include any 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** is needed for *all* of the following design parameters for the predicate and new tobacco products:

a. Puff count
b. Cigarette draw resistance (mm H_2O)
c. Tobacco filler mass (mg)
d. Tobacco oven volatiles (OV) (%)
e. Filter ventilation (%)
f. Cigarette paper base paper basis weight (g/m^2)
g. Cigarette paper base paper porosity (CU)
h. Cigarette paper band porosity (CU)
i. 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)]
j. Filter pressure drop (mm H_2O)

Certificates of analysis from the material supplier may satisfy this deficiency. The certificates of analysis would need to include a target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data.

8. Your SE Report does not provide any information regarding the heating source for the new and predicate tobacco products. A description of the heating source is necessary for product characterization as defined in section 910(a)(3)(B) of the FD&C Act.

9. Your SE Report lacks the basis for your determination that the new tobacco product is substantially equivalent to a predicate tobacco product. The basis for your determination is that the new tobacco product either (1) has the same characteristics as the predicate tobacco product (in accordance with section 910(a)(3)(A)(i) of the FD&C Act), or (2) has different characteristics than the predicate tobacco product but the new tobacco product does not raise different questions of public health (in accordance with section 910(a)(3)(A)(ii) of the FD&C Act). As a reminder, characteristics, as used in the definition of substantial equivalence, is defined at section 910(a)(3)(B) of the FD&C Act as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

10. Your SE Report lacks an adequate summary of any health information related to your new tobacco product or a statement that such information will be made available upon request (section 910(a)(4) of the FD&C Act). Note that this requirement is separate from the requirement of section 904(a)(4) of the FD&C Act to submit certain health documents. In future submissions, if a health information summary is included, it should contain detailed information regarding data concerning adverse health of the new tobacco product.

11. Your SE Report lacks a statement of your action to comply with any standards under section 907 of the FD&C Act (see section 905(j)(1)(B) of the FD&C Act), including those standards under section 907(a) of the FD&C Act and any promulgated through regulation.

You have failed to 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. 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.

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 SE0010227

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.

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 SE0010227**. 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.

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/NewTobacco ProductReviewandEvaluation/default.htm.

If you have any questions, please contact Ryan Nguy, Regulatory Health Project Manager, at (301) 796 - 7079.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.10.05 15:38:42 -04'00'

David L. Ashley, Ph.D.
RADM, United States Public Health Service
Office of Science
Center for Tobacco Products