DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

October 18, 2016

NOT SUBSTANTIALLY EQUIVALENT

Liggett Group LLC
Attention: John Long, Vice President & General Counsel
3800 Paramount Parkway, Ste. 250
Morrisville, NC, 27560

FDA Submission Tracking Number (STN): SE0000357

Dear Mr. Long:

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:	Liggett Group LLC
Tobacco Product Name[1]:	Class A Menthol Silver 100's Soft Pack
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 Cigarettes
Length:	99 mm
Diameter:	7.8 mm
Filter Ventilation:	54%
Characterizing Flavor	Menthol

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

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:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Liggett Group LLC
Tobacco Product Name[2]:	Liggett Select Ultra Lights 100's Soft Pack
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Combusted, Filtered
Package Type:	Soft Pack
Package Quantity:	20 Cigarettes
Length:	99 mm
Diameter:	7.8 mm
Filter Ventilation:	58%
Characterizing Flavor:	None

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 menthol is added as a characterizing flavor to the new tobacco product, whereas the predicate tobacco product does not contain a characterizing flavor. The addition of menthol as a characterizing flavor is likely associated with increased smoking initiation (e.g., increasing palatability), increased level/severity of dependence (e.g., increasing abuse liability), and/or decreased likelihood of cessation for the new tobacco product compared to the predicate tobacco product. Therefore, the addition of menthol causes the new tobacco product to raise different questions of public health.

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. You cannot distribute, import, sell, market, or promote this product in the United States. Doing so is a prohibited act under section 3301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

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

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 lists significant differences in tobacco blends of the new tobacco product compared to predicate tobacco products. For example, you report (b) (4) (b) (4), and (b)(4) and reconstituted tobacco in the new tobacco product compared to the predicate tobacco product. Tobacco blend changes have been shown to affect HPHC quantities. It has been reported that the mainstream smoke of (b)(4) and reconstituted tobacco tends to contain much higher levels of TSNAs than the smoke of (b) (4), whereas that of (b) (4) tends to contain higher levels of benzo[a]pyrene (B[a]P) than other types of tobacco. Therefore, the differences in tobacco blend may potentially affect the smoke chemistry. Your SE Report lacks scientific evidence and rationale as to why the blend differences do not cause the new tobacco product to raise different questions of public health. Such evidence may include HPHC yields (e.g., NNN, NNK, and B[a]P) under both the ISO and Canadian Intense smoking regimens.

3. Your SE Report indicates that the variability for tobacco quantities is uniformly (b) (4) percent and that the variability for the quantities of ingredients other than tobacco is uniformly (b) (4) percent. You have not specified whether the reported variabilities are experimental or theoretical, or whether the variabilities represent ranges, standard deviations or standard errors.

4. Your SE Report provides information about tobacco and ingredients added to tobacco in the predicate and new tobacco products. However, your SE Report does not include ingredients in all components of the predicate and new tobacco products (e.g., cigarette paper, filter, plug wrap, tipping paper, adhesives, and additives under “Materials” of Exhibit A). Without this information, we cannot determine whether the predicate and new tobacco products are substantially equivalent. Additionally, the information provided for tobacco and ingredients does not include sufficient detail to fully identify the 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. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both 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 new and predicate products. Similarly, for other ingredients, it would be helpful to know the grade of each ingredient. In addition, you do not identify the tobacco(s) or other ingredients found in the reconstituted tobacco. It is important to know what ingredients, specifically, are included in the reconstituted tobacco in order to ensure that the tobacco blend differences do not cause the new products to raise different questions of public health. Ingredient information needed to fully characterize the predicate and new tobacco products includes the following:

a. Ingredients for all components (e.g., cigarette paper, filter, plug wrap, tipping paper, adhesives, and additives under "Materials" of Exhibit A)
b. Ingredients for reconstituted tobacco
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)
d. Information to uniquely identify all ingredients (e.g., CAS #, grade/purity)

5. Your SE Report indicates that the new tobacco product includes FSC cigarette paper containing (b) (4) as compared the predicate tobacco product, which includes FSC paper containing (b) (4) (b) (4) These different types of paper and banding materials may produce different types and quantities of ingredients when they are burned. The burning of (b)(4) in the paper of the new tobacco product may result in increased levels of several HPHCs including acetaldehyde, benzene, and formaldehyde. Your SE Report lacks scientific evidence and rationale for why the difference in cigarette paper does not cause the new tobacco product to raise different questions of public health.

6. Your SE Report lists some ingredient quantities as percentages by weight. For example, the amount of (b) (4) in cigarette paper is expressed as (b) (4) and (b) (4) (or (b) (4)). In order for FDA to fully and clearly characterize the new and predicate tobacco products, all of the ingredient quantities are needed on a mass per unit of use basis (i.e., mg/cigarette).

7. Your SE Report includes data comparing HPHC quantities in the predicate and new tobacco products. However, your SE Report lacks the following information necessary to fully evaluate the data:

   a. Quantitative methods used
   b. Testing laboratory or laboratories
   c. Length of time between date(s) of manufacture and date(s) of testing
   d. National/international standards used and any deviation(s) from those standards
   e. Storage conditions prior to initiating testing

   In addition, your SE Report does not provide full test data (including test protocols, any deviations from test protocols, quantitative acceptance (pass/fail) criteria, and complete data sets) for all testing performed.

8. Your SE Report includes TNCO yields from the new and predicate tobacco products. However, your SE Report does not provide mean values and, instead, includes relatively wide ranges of yields for each HPHC. The ranges for TNCO yields are identical for the new and predicate tobacco products. Mean values and variance (rather than ranges) are needed for TNCO yields under both ISO and Canadian Intense smoking regiments. Also, clarification is needed for why the ranges are identical for the new and predicate products, including clarification about whether the values are measured values and/or estimated/calculated values.

9. Your SE Report states that the tipping paper [redacted] has changed from [redacted] in the predicate tobacco product to [redacted] in the new tobacco product. However, the chemical composition for these [redacted] is not provided. If the ink ingredients are different between the new and predicate tobacco products, scientific evidence and rationale would be needed as to why the differences would not cause the new tobacco product to raise different questions of public health.

10. Your SE Report notes the addition of more than [redacted] of menthol to the inner foil of the cigarette packet of the new tobacco product. In order to fully characterize the predicate and new tobacco products, additional information about the packaging is needed. Such information includes a detailed ingredients list for the wrap, foil and cardboard packaging of the new and predicate tobacco products.

11. Your SE Report provides information on some of the design parameters for the new and predicate tobacco products. However, your SE Report does not include **target specification and upper and lower range limits** for *all* of the following design parameters necessary to fully characterize the new and predicate tobacco products:

    a. Tipping paper length (mm)
    b. Cigarette paper base paper basis weight (g/m^2)
    c. Cigarette paper band porosity (CU)
    d. Cigarette paper band width (mm)
    e. Cigarette paper band space (mm)
    f. 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, your SE Report does not include the **target specifications** for the following design parameter for the new and predicate tobacco products:

    g. Cigarette paper base paper porosity (CU)

    If differences exist between the new and predicate tobacco products, scientific evidence and rationale would be needed to demonstrate that the differences do not cause the new tobacco product to raise different questions of public health.

12. Your SE Report includes design parameter specifications but none 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** is needed for *all* of the following design parameters for the new and predicate tobacco products:

    a. Puff count
    b. Cigarette draw resistance (mm H2O)
    c. Tobacco filler mass (mg)
    d. Tobacco oven volatiles (OV) (%)

e. Filter ventilation (%)
f. Cigarette paper base paper basis weight (g/m2)
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 H2O)

13. Your SE Report indicates that the new tobacco product has multiple plug wrap paper materials and the predicate tobacco product has multiple cigarette base paper materials. In accordance with section 910(a)(1)(B) of the FD&C Act, each product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette base paper and plug wrap paper materials. However, your SE Report does not identify the following:

    a. Every unique material combination in the predicate tobacco products that was on the market as of February 15, 2007
    b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. Each specific combination of materials will be considered a single new tobacco product and evaluated individually in accordance with Section 910(a)(2)(B) of the FD&C Act.

    For each identified new and predicate tobacco product, based on each combination of cigarette base paper and plug wrap paper materials, data generated from testing of design parameters and HPHCs is needed.

14. Your SE Report indicates that the pressure drop in both the overall cigarette and filter are almost exactly the same. It is unclear how these values can be the same when the pressure drop of the tobacco rod generally causes the overall pressure drop to be greater than the filter pressure drop alone. Additionally, your SE Report states that any changes in pressure drop "merely reflects a correction in the pressure drop target to reflect the actual pressure drop, as measured during routine quality control monitoring." This statement implies that you are changing the target specification to fit changing test data, which then makes it difficult to accurately characterize the product. However, your SE Report states that the target specification and manufacturing process are not changing. Therefore, clarification of the overall cigarette and filter pressure drop is needed along with scientific rationale and evidence for any differences that may cause the new tobacco product to raise different questions of public health. In addition, a rationale is needed to demonstrate that shifting the target specification for cigarette draw resistance does not create a difference in product characteristics. Lastly, a revised procedure to ensure future target specifications will not be altered based on changing test data is needed.

15. Your SE Report indicates that the filter ventilation decreased in the new tobacco product relative to the predicate tobacco product. Your SE Report states that the decrease in filter

ventilation is to keep tar values consistent. However, your SE Report provides large ranges of TNCO values that may result in large differences in TNCO yields between the new and predicate tobacco products. Furthermore, a decrease in filter ventilation decreases the dilution of inhaled smoke and is likely to cause an increase in smoke constituent yields. Therefore, a scientific rationale and evidence is needed to demonstrate that the difference in filter ventilation does not cause the new tobacco product to raise different questions of public health.

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 SE0000357

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 CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[3] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter), or mail to:

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

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 both generally available 24 hours a day, seven days a week. Submissions delivered to DCC by couriers 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 the prior business day. We are unable to accept regulatory submissions by e-mail.

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 SE0000357.** 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/default.htm.

If you have any questions, please contact Khemry Min, MHA, Regulatory Health Project Manager, at (240) 402 - 4485.

Sincerely,

Digitally signed by David Ashley -S
Date: 2016.10.18 13:12:33 -04'00'

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