DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 15, 2015

NOT SUBSTANTIALLY EQUIVALENT

R.J. Reynolds Tobacco Company
Attention: James E. Swauger, Ph.D., DABT
Vice President, Regulatory Oversight, RAI Services Company
401 N. Main Street, P.O. Box 2959
Winston-Salem, N.C. 27101

FDA Submission Tracking Number (STN): SE0000277

Dear Dr. Swauger:

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:	R.J. Reynolds Tobacco Company
Tobacco Product Name[1]:	Vantage Tech 13
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Filtered, Combusted
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	83 mm
Diameter:	7.8 mm
Filter Ventilation:	25%

[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:	R.J. Reynolds Tobacco Company
Tobacco Product Name[2]:	Camel Light Hard Pack
Tobacco Product Category:	Cigarette
Tobacco Product Sub-Category:	Filtered, Combusted
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	None
Length:	83 mm
Diameter:	7.8 mm
Filter Ventilation:	25%

We have described below our basis for this determination.

1. Your SE Report does not provide target specifications and upper and lower range limits for all design parameters. The following additional information is required in order to adequately characterize the new and predicate tobacco products:

    a. Your SE Report provides target specifications and range limits for cigarette paper band diffusivity for the new and predicate tobacco products and cigarette paper band porosity for the predicate tobacco products. Band porosity measures permeability which allows for the overall assessment of the change or weighted change in air flow through the cigarette paper during active puffing. Therefore, target specifications and upper and lower range limits for cigarette paper band porosity is needed for the new and predicate tobacco products. Or, a correlation between diffusivity and porosity is needed to allow for a scientific comparison of the two parameters.
    b. Your SE Report does not include the upper and lower range limits for filter total denier and denier per filament in the new and predicate tobacco products.

    For the parameters above, if a difference exists between the new and predicate tobacco products, scientific evidence is needed to demonstrate that the difference does not cause the new tobacco product to raise different questions of public health.

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

2. Your SE Report does not contain all of the necessary testing information to confirm the target specifications are met. In order to fully evaluate whether or not the target specifications are met, all of the following information is needed:

    a. Full test data (including test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for filter density, filter total denier, filter denier per filament, plug wrap length, cigarette paper base paper basis weight, and cigarette paper base paper porosity for the new and predicate tobacco products
    b. Full test data (including test protocols, quantitative acceptance criteria, data sets, and a summary of the results) for cigarette paper band porosity for the new and predicate tobacco products and the quantitative acceptance criteria for the cigarette paper band porosity of the new tobacco product

    Certificates of analysis (COAs) from the material supplier may satisfy this deficiency if the COAs 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.

3. Your SE Report provides the upper and lower range limits for filter pressure drop in the new tobacco product. Your SE Report explains that the filter rods are manufactured independently of the cigarettes and, in turn, may have different range limits compared to the individual filter segments that are subject to further manufacturing and incorporated into the cigarette. The supplier's COA pertains to the filter rod, not the filter segment. However, your SE Report explains that, as a result of the variability when the rod is cut, your range limits are slightly wider than the supplier's range limits. It is unclear how the filter segment lengths vary when the cutting process is precise to (b) (4). Furthermore, if the filter length ranges are tight, the filter pressure drop ranges should mimic closely. Typically, the filter segment pressure drop is very similar, if not equal, to the filter rod pressure drop when divided by the cut number. You have not justified how the segment length difference translates into the pressure drop difference apparent between your range limits and the supplier's range limits.

4. Your SE Report indicates that the new tobacco product produces significantly higher yields of numerous HPHCs compared to the predicate tobacco product. Your SE Report provides a Quantitative Risk Assessment (QRA) which you claim demonstrates that the significant increases in HPHC yields in the new tobacco product do not raise different questions of public health. However, the submitted QRA is not adequate to demonstrate substantial equivalence for the following reasons:

    - The QRA is based on estimates of statistical variation that were derived from HPHC data from >100 cigarette brands and no evidence was provided to demonstrate that the data can be extrapolated to the new and predicate tobacco products.

- The QRA includes HPHC data that used the ISO smoking regimen for some HPHCs and the CI smoking regimen for other HPHCs, resulting in the summing of calculated risks based on different smoking regimens.
- The QRA did not use important inhalation dosimetry parameters such as those listed in the updated USEPA RAGS F guideline.

Therefore, scientific evidence and discussion is needed to explain how the significant increases in HPHC yields do not cause the new tobacco product to raise different questions of public health.

In addition to these deficiencies, it should be noted that the tobacco blend in the new and predicate tobacco products was not fully characterized because you provided quantities as percentages and did not provide information in order to determine absolute quantities of each tobacco (in milligrams per cigarette). If you choose to submit a new SE Report for the new tobacco product in the future, you should provide tobacco quantities in absolute values.

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 SE0000277

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 SE0000277.** 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 Kim Collins, Lead Regulatory Health Project Manager, at (301) 796-1556.

Sincerely,

Digitally signed by David Ashley -S
Date: 2015.09.15 06:44:42 -04'00'

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