DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

April 03, 2018

SUBSTANTIALLY EQUIVALENT

Republic Tobacco, LP
Attention: Carl Ioos, Senior Vice President
2301 Ravine Way
Glenview, IL 60025

FDA Submission Tracking Number (STN): SE0014368

Dear Mr. Ioos:

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 (the FD&C Act), for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	Republic Tobacco, LP
Tobacco Product Name[1]:	Top Standard
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Rolling Paper
Package Type:	Booklet
Package Quantity:	125 papers
Characterizing Flavor[2]:	None
Length:	70 mm
Width:	39 mm
Additional Properties:	Paper 2

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

[2] As provided by applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Based on our review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following tobacco product[3], for which FDA has previously issued an order of substantial equivalence under SE0012913:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Republic Tobacco, LP
Tobacco Product Name[4]:	Top Standard
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Rolling Paper
Package Type:	Booklet
Package Quantity:	100 papers
Characterizing Flavor:	None
Length:	70 mm
Width:	39 mm

Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you opted not to provide an adequate summary of any health information related to the new tobacco product with your application, but stated that such information will be available upon request by any person. Consistent with the requirements of Section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Report upon which our order was based, redacted only to the extent necessary to exclude patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR § 20.61 and 20.63 and;
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

[3] In addition to comparing the new tobacco product to the predicate tobacco products named by the applicant, FDA also compared the new tobacco product in this SE Report to the grandfathered tobacco product in SE0012913. Although the new product has different characteristics than the grandfathered tobacco product in SE0012913, FDA found that those differences do not cause the new tobacco product to raise different questions of public health, and thus the new tobacco product is also substantially equivalent to the grandfathered product in SE0012913.

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

Alternatively, you may provide the following when information is requested:

A. Description of the new tobacco product;
B. Description of the predicate tobacco product;
C. List of all differences in characteristics between the predicate and new tobacco products;
D. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health; and
E. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

There may be other accurate, complete and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product[5]. Our finding does not mean FDA "approved" the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product[6] is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming.

[5] Please see footnote 2.

[6] Please see footnote 2.

FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[7] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed 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 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.

If you have any questions, please contact Nicholas Hasbrouck, Regulatory Health Project Manager, at (240) 402 - 5413.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.04.03 13:34:55 -04'00'

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

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