DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

August 16, 2017 **SUBSTANTIALLY EQUIVALENT**

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

FDA Submission Tracking Number (STN): SE0013919

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

New Tobacco Product

Tobacco Product Manufacturer:	Republic Tobacco, LP
Tobacco Product Name[1]:	High Card Regular King Size
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Filtered Cigarette Tube
Package Type:	Box
Package Quantity:	250 tubes
Length:	84 mm
Diameter:	8.11 mm
Ventilation:	(b) (4)
Characterizing Flavor[2]:	None

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

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] As provided by applicant's certification statement. FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

tobacco product[3], for which FDA has previously issued an order of substantial equivalence under SE0004370:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Republic Tobacco, LP
Tobacco Product Name[1]:	High Card Regular King Size
Tobacco Product Category:	Roll-Your-Own Tobacco
Tobacco Product Sub-Category:	Filtered Cigarette Tube
Package Type:	Box
Package Quantity:	200 tubes
Length:	84 mm
Diameter:	8.11 mm
Ventilation:	(b) (4)
Characterizing Flavor[2]:	None

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 submitted a summary of any health information related to the tobacco product in your SE Report and provided a statement that any such information will be available upon request by any person. No later than 30 days from the date of this letter, we will make your summary available to the public.

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[3]. 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[3] 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

[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 SE0004370. Although the new product has different characteristics than the grandfathered tobacco product in SE0004370, 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 SE0004370.

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. 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)[4] 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.

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

If you have any questions, please contact Sarah Webster, Regulatory Health Project Manager, at (301) 796 - 7939.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2017.08.16 10:21:32 -04'00'

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