



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 08, 2017

**EXEMPT**

R.J. Reynolds Tobacco Company  
Attention: James Figlar, Ph.D.  
Senior Vice President, Scientific & Regulatory Affairs  
RAI Services Company  
401 North Main Street  
Winston-Salem, NC 27101

**FDA Submission Tracking Number (STN): EX0000185**

Dear Dr. Figlar:

The Food and Drug Administration (FDA) completed review of your Request for Exemption from Substantial Equivalence (EX REQ), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the following tobacco product:

<b>Tobacco Product Manufacturer:</b>	R.J. Reynolds Tobacco Company
<b>Tobacco Product Name:</b> <sup>1,2</sup>	Newport Box
<b>Tobacco Product Category:</b>	Cigarettes
<b>Tobacco Product Sub-Category:</b>	Combusted, Filtered
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Length:</b>	80 mm
<b>Diameter:</b>	7.9 mm
<b>Ventilation:</b>	0%
<b>Characterizing Flavor:</b>	Menthol
<b>Modification:</b>	Substitution/Deletion of tobacco additives: substitution of non-FSC <sup>3</sup> cigarette paper with FSC cigarette paper
<b>Additional Property:</b>	FSC Paper 2 ( (b) (4) )

Based on our review of your EX REQ, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and exempt from the requirements of Substantial Equivalence under section 910(a)(3)(A).

<sup>1</sup> Brand/sub-brand or other commercial name used in commercial distribution

<sup>2</sup> The name of the tobacco product being modified is Newport Menthol Box

<sup>3</sup> Fire Standards Compliant

**To market the new tobacco product that is the subject of this EX REQ, the following must be met:**

- 1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
- 2. Ninety days have passed since FDA receipt of your Abbreviated Report.**

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

Our finding does not mean FDA “approved” the modified tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the modified 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](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto: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>)<sup>4</sup> 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  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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<sup>4</sup> The FDA’s Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

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 Jennifer Schmitz, Regulatory Health Project Manager at (240) 402-5892.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2017.09.08 15:04:53 -04'00'

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