DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 09, 2015

EXEMPT

American Snuff Company, LLC
Attention: James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight, RAI Services Company
401 N. Main Street
P.O. Box 464
Winston-Salem, NC 27102

FDA Submission Tracking Number (STN): EX0000026

Dear Dr. Swauger:

The Food and Drug Administration (FDA) completed review of your June 27, 2012, Request for Exemption from Substantial Equivalence (EX Request) under section 905(j)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) for the following product:

Tobacco Product Manufacturer:	American Snuff Company, LLC
Tobacco Product Name[1]:	Grizzly Long Cut Mint
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Loose Moist Snuff
Package Type:	Can
Package Quantity:	1.2 oz
Characterizing Flavor:	Mint
Tobacco Particle Size:	Long Cut[2]
Modification:	Substitution of (b) (4) water (b) (4) from (b) (4) (b)(4) (b) (4) sodium chloride (b) (4) from (b) (4)

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] As provided by applicant. For purposes of an EX Request, a numerical value is not necessary as the tobacco itself cannot be modified as the exemption is limited to additives.

Based on the information in your EX Request, the new tobacco product specified in the table above is **Exempt** from the requirements of Substantial Equivalence under section 910(a)(3)(A) of the FD&C Act. To market the new tobacco product that is the subject of this EX Request the following must be met:

1. You 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 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. This marketing order is subject to reconsideration and rescission to the extent authorized by law. See 21 C.F.R. 1107.1(d).

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. A review of labeling and advertising was not conducted as part of our review of your request for an exemption from substantial equivalence. 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 remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by 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 are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Kim Collins, Regulatory Health Project Manager, at (301) 796 – 1556.

Sincerely yours,

Digitally signed by David Ashley -S
Date: 2015.04.09 18:14:29 -04'00'

David L. Ashley, PhD
RADM, US Public Health Service
Director, Office of Science
Center for Tobacco Products