



RAI Services Company

James N. Figlar, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
Winston-Salem, NC 27101
336-741-7818
Fax: 336-728-9062
figlarj@rjrt.com

CONFIDENTIAL, NOT FOR PUBLIC DISCLOSURE

October 4, 2017

Jennifer Schmitz, MPH
Regulatory Health Project Manager
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

Re: AMENDMENT TO MODIFIED RISK TOBACCO PRODUCT APPLICATIONS for MR0000068-MR0000073

Dear Ms. Schmitz:

RAI Services Company ("RAIS")¹, on behalf of R.J. Reynolds Tobacco Company ("RJRT"), hereby submits the following amendment to Applications Seeking a Modified Risk Tobacco Product Order ("MRTP Applications"), submitted under Section 911(d) of the Food, Drug, and Cosmetic Act ("FDCA") on March 30, 2017 for the following tobacco products:

- Camel Snus Frost (MR0000068);
- Camel Snus Frost Large (MR0000069);
- Camel Snus Mellow (MR0000070);
- Camel Snus Mint (MR0000071);
- Camel Snus Robust (MR0000072);
- Camel Snus Winterchill (MR0000073).

¹ RAI Services Company ("RAIS") bears primary responsibility for regulatory compliance for Reynolds American Inc.'s operating companies, including R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Co., LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("SFNTC"), R.J. Reynolds Vapor Company, and Kentucky BioProcessing, Inc. ("KBP"). References to RAIS in this letter refer to itself and its affiliated companies where applicable.

This amendment addresses two (2) individual pages within the MRTPAs which contain typographical errors. As agreed upon with FDA², RAIS is providing two (2) replacement pages, along with versions which include previously proposed redactions, to address the following typographical errors:

- On Page 89 of Section 2, specifically Section 2.6.2, the word “can” has been added between “SNUS” and “greatly”. Replacement pages are provided herein as [Section 2, P.89](#) and [Section 2, P.89 Redacted](#).
- On Page 65 of Section 3.1-3.2, specifically Section 3.2.3.1.1, (b) (4) has been changed to (b) (4) and “-(b) (4)” has been changed to “(b) (4)”. Replacement pages are provided herein as [Section 3.1-3.2, P.65](#) and [Section 3.1-3.2, P.65 Redacted](#).

Please note that the enclosed response may contain confidential commercial and non-public trade secret information belonging to RAIS, RJRT, or RJRT’s vendors. All such confidential and trade secret information is exempt from public disclosure under § 301(j) and § 906(c) of the FDCA, 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905, and 21 C.F.R. § 20.61 and any similar or related laws and regulations. RAIS and RJRT respectfully request that FDA maintain the confidentiality of this information.

Should you have any questions or require any additional information, please contact me at your earliest convenience.

Respectfully submitted,



James N. Figlar, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
RAI Services Company

² A discussion regarding the format of this amendment occurred during a October 2, 2017 teleconference initiated by Dr. Michael Borgerding of RAIS. Ms. Jennifer Schmitz participated in the call on behalf of FDA.