

RAI Services Company

Michael W. Ogden, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
336-741-5787
Fax: 336-728-7675
ogdenm@rjrt.com

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June 13, 2018

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

RECEIVED
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BY: CTP/DCC

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 ("RJRT"), 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 ("FD&C Act") 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 RAIS is a wholly owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for regulatory compliance for RAI's operating companies, including R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Company, LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("SFNTC") and R.J. Reynolds Vapor Company ("RJRV"). References to RAIS in this letter include itself and RJRT, where applicable.

On October 4, 2017, RAIS corrected (b) (4) used in the production of Camel Snus within Sections 3.1 - 3.2, specifically Section 3.2.3.1.1 on page 65 of the applications, MR0000068-MR0000073. However, RAIS failed to update the (b) (4) associated with this corrected (b) (4) information. RAIS would like to correct the record as it relates to this error. RAIS notes that (b) (4), as described in section 3.2.3.1.1 of these applications.

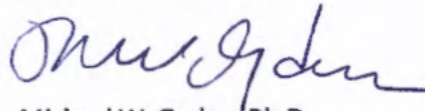
As seen in Appendix A, RAIS has itemized the discrepancy by page number, noted the erroneous information, and provided the corrected values or text. Appendix B contains the Certificates of Material and Manufacture Conformity (COCs) from the material supplier for both the (b) (4) described in section 3.2.3.1.1 and the October 4, 2017 amendment. These COCs reflect (b) (4). Please advise should FDA prefer a revised version of the affected sections.

Please note that the enclosed response does contain confidential commercial and non-public trade secret information belonging to RAIS, RJRT, or RJRT's vendors. As such, RAIS is providing both an original version of this amendment and a redacted version for posting to the public docket.

All such confidential and trade secret information is exempt from public disclosure under § 301(j) and § 906(c) of the FD&C Act, 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,



Michael W. Ogden, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
RAI Services Company