



RAI Services Company

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March 5, 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



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 ("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 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.

This amendment addresses FDA's questions from the February 28, 2018 teleconference with representatives from RAIS.² In order to be responsive to FDA's questions, RAIS will repeat their understanding of FDA's specific questions in bold and italics and follow with RAIS' response.

1. *Figure 3.2-6 illustrates the manufacture of Camel Snus* (b) (4)

(b) (4)

as described in this figure?

(b) (4) described in Table 3.2-8 are produced

(b) (4)

as illustrated in Figure 3.2-6. (b) (4)

(b) (4)

2. *Figure 3.2-3 illustrates the Snus process* (b) (4). ***Will RAIS please provide the address***

(b) (4) ***for processing?***

(b) (4)

3. *Are there any other locations related to the manufacture of Camel Snus* (b) (4)

?

(b) (4)

² Please refer to the February 28, 2018 teleconference between representatives from FDA including Jennifer Schmitz, MPH, Mimy Young, Marcella White, Hans M. Rosenfeldt, Ph.D., and Chad Burger with Michael F. Borgerding, Ph.D. and Summer N. Hanna, Ph.D. of RAIS.

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,

A handwritten signature in blue ink, appearing to read "Michael W. Ogden".

Michael W. Ogden/Ph.D.

Senior Vice President

Scientific & Regulatory Affairs

RAI Services Company

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