



RAI Services Company

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February 6, 2018

Ann Simoneau
Director, Office of Compliance and Enforcement
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: Response to Office of Compliance and Enforcement request for MR0000068 Camel Snus Frost; MR0000069 Camel Snus Frost Large; MR0000070 Camel Snus Mellow; MR0000071 Camel Snus Mint; MR0000072 Camel Snus Robust; MR0000073 Camel Snus Winterchill

Dear Ms. Simoneau:

RAI Services Company ("RAIS")¹ hereby submits the following, on behalf of R.J. Reynolds Tobacco Company ("RJRT"), in response to the United States Food and Drug Administration's ("FDA") Center for Tobacco Products ("CTP") January 24, 2018, INSPECTION REQUEST letter regarding RAIS' submission of 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);

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"), and R.J. Reynolds Vapor Company. References to RAIS in this letter refer to itself and its affiliated companies where applicable.

- Camel Snus Winterchill (MR0000073).

This letter includes responses to items #1 and #2 from FDA's January 24, 2018 letter which request that certain information be provided to FDA. In this response, we have repeated CTP's requests, verbatim and in bold italics, followed by RAIS' response.

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.

RAIS looks forward to the opportunity for this inspection. Please let us know FDA's preferred dates for the inspection and we will make any necessary final arrangements. 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 "M. Ogden", with a long horizontal flourish extending to the right.

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

FDA Requests

1. *[Specifically, FDA requests that:] You provide complete contact information (address, phone number, fax number and email address), including the name of the point of contact and the name of the owner or operator of the facility for each of the above facilities.*

RAIS RESPONSE

RAIS understands from FDA's letter that information is requested regarding a point of contact for facilities that will be inspected as part of the MRTPA review process and notes that RAIS bears responsibility for coordinating all such inspection activities. As such, please contact me as the primary point of contact for the inspection.

In addition, requested information is provided for manufacturing and leaf buying activities related to Camel Snus in the following table.

(b) (4)

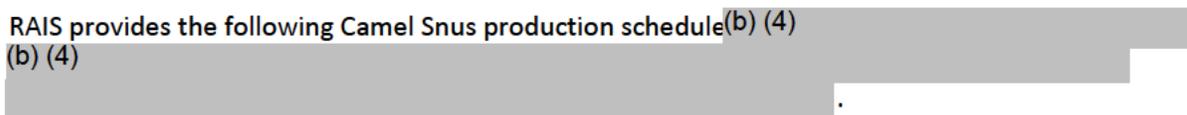


2. *[Specifically, FDA requests that:] You provide production schedules of the manufacturing activities performed at each facility for the MRTPA products referenced above to ensure that inspections coincide with the production of these products.*

RAIS RESPONSE

RAIS provides the following Camel Snus production schedule (b) (4)

(b) (4)



Camel SNUS Production Schedule (subject to revision)

(b) (4)

