



RAI Services Company

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August 16, 2017

Benjamin Apelberg, Ph.D.
Director, Division of Population Health Science
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: PARTIAL RESPONSE (ITEM 10) to July 25, 2017 INFORMATION REQUEST for MR0000068-MR0000073

Dear Dr. Apelberg:

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") July 25, 2017, ADVICE/INFORMATION 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);
- 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 response refers to Item Ten (10) in the aforementioned information request. Items not addressed in this document will be covered in separate responses. 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.

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

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Figlar', with a large, stylized initial 'J' and a long, sweeping horizontal stroke extending to the right.

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

FDA-Listed Deficiencies and RAIS Response

10. All of your MRTPAs describe, as part of your proposed post-market surveillance program in Section 9.4.6.2., the Total Tobacco Migration Tracker (TTM), which “assesses adult tobacco users’ attitudes and behaviors across a number of tobacco products” through monthly surveys of adults. Your MRTPAs state that “the methodological report for TTM will be finalized and submitted to the FDA with the final Post-Market Surveillance Program Protocol.” It is unclear whether you have already generated analyses and findings from this ongoing survey system. Providing this information can inform Camel Snus user characteristics and tobacco use behaviors. If ongoing analyses or reports have been generated using the TTM, provide them as well as the underlying materials related to the development, conduct and current findings.

RAIS RESPONSE

No analyses have been conducted, and no findings or reports generated on adults’ attitudes or use behaviors related to Camel Snus using data from the Total Tobacco Migration Tracker (TTM).

RJRT has proposed, as one component of a post-market surveillance plan, to collect information on adults’ attitudes and use behaviors related to tobacco products, including Camel Snus, using this survey instrument. TTM has been undergoing review and revision to improve its effectiveness as a post-market surveillance instrument, in the event that Camel Snus receives a modified risk tobacco product order. To achieve this goal, the methodological report for TTM was finalized in July 2017, and quality control and data cleaning efforts are in progress.