



RAI Services Company

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**CONFIDENTIAL, NOT FOR PUBLIC DISCLOSURE**

August 17, 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 5) to July 25, 2017 INFORMATION REQUEST for MR0000068-MR0000073**

Dear Dr. Apelberg:

RAI Services Company ("RAIS")<sup>1</sup> 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).

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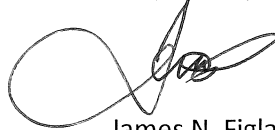
<sup>1</sup> RAI Services Company ("RAIS") bears primary responsibility for regulatory compliance for Reynolds American Inc.'s operating companies, including R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Co., LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("SFNTC"), R.J. Reynolds Vapor 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 Five (5) 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 loop at the beginning.

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

FDA-Listed Deficiencies and RAIS Response

5. ***All of your MRTPAs contain a published paper on the assessment of mouth-level exposures in U.S. Camel snus users (Caraway and Chen, 2013), work supported by RJRT, a description of the statistical methods used, and folders containing raw and analyzed data in Section 7.4, folder "02\_CSD0804\_SMA." We could not find the final clinical study report, protocol, and programming code from this study within your applications. We also could not find case report forms for any deaths, other serious and unexpected adverse experiences, or discontinuations from this study. These documents inform the evaluation of study validity and the effect of the products on tobacco-related diseases and health-related conditions pertinent to your applications. Submit this information related to this research study or indicate the exact location within your MRTPAs where these materials can be found.***

RAIS RESPONSE

The referenced published paper on the assessment of mouth-level exposures in U.S. Camel Snus users (Caraway and Chen, 2013) summarizes the findings of study CSD0804. The Snus After Use – Market Adopter Pilot Study (CSD0804) was conducted using a marketing research firm and was not conducted using a clinical site nor in accordance with the International Conference on Harmonization Guideline for Good Clinical Practice. However, volunteers who participated in the study provided written informed consent prior to their enrollment. Study product was not provided to subjects, and subjects used their own usual brand product purchased by them during the study. Neither a clinical study report nor case report forms were created for this study; thus, they do not exist. Study procedures were not invasive and risk to the subjects from study procedures was minimal as the study focus was collection of used Camel Snus product. Adverse event reports were not collected during the study. Discontinuations were recorded by the marketing research firm who conducted the study. Two subjects (block numbers 56 and 58) did not return for their second study visit and were discontinued from the study, as referenced in an email between RJRT and Bellomy Research, submitted herein as [q05-discontinuation-email-0804](#). The protocol for study CSD0804 is submitted herein as [q05-CSD0804\\_Protocol\\_2008\\_08\\_04\\_final fully signed](#). In addition, the final test report concerning chemical analyses of used and unused Camel Snus is submitted herein as [q05-M98-Report-R1-31Mar2017](#). As noted in the chemical analysis final test report, one participant used more than one Camel Snus brand style and was excluded from data analysis. Statistical analyses were performed using JMP software (SAS Institute Inc., Cary, NC 27513), which utilizes a graphical user interface instead of programming code. Consequently, no programming code is available to provide.