



RAI Services Company

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October 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 9) 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 Nine (9) in the aforementioned information request. RAIS is submitting this response on electronic media through the FDA Document Control Center as it includes an appended file with an extension (.sas7bcat) which is incompatible with CTP's eSubmitter tool. Items not addressed in this document will be covered in separate responses which will be transmitted through the CTP Portal using the eSubmitter tool. 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', written over a large, loopy circular flourish.

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

FDA-Listed Deficiencies and RAIS Response

9. ***All of your MRTPAs provide statistical data and associated analysis code in several sections. In Section 7.4 (03_CSD0901_SSSO), you included a file: "sasmacr.sas7bcatsas" that we are unable to open. This file appears to be a SAS macro catalog that was created in 32-bit format. Our machines use 64-bit. Submit the file in a format that is compatible with 64-bit SAS.***

RAIS RESPONSE

A SAS macro catalog for clinical study CSD0901 that is compatible with 64-bit SAS has been produced and provided within this electronic media as the file "q09-csd0901-macrocatalog-64bit.sas7bcatsas".