



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 1) 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 One (1) 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 'James N. Figlar', with a large, stylized initial 'J' and a long horizontal flourish extending to the right.

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

FDA-Listed Deficiencies and RAIS Response

- 1. All of your MRTPAs include several R.J. Reynolds Tobacco Company (RJRT) sponsored studies “to characterize the chemistry of Camel Snus products in relation to cigarettes and other U.S. smokeless tobacco products” (Section 6.1.5.4, p. 25). We cannot locate the following documents that pertain to these studies:**

- a. Datasets for studies RDM JAB 2016, 306 (Market Survey of U.S. cigarettes to determine harmful and potential harmful constituent (HPHC) content of smoke), RDM JAB 2016, 281 (Market Survey of U.S. smokeless tobacco products (including Camel Snus) to determine HPHC content) and LSI 2016 097 (Characterization of Tobacco-Minor Alkaloids), discussed in Section 7_1**

RAIS RESPONSE

The datasets referenced in Item One (1) for studies RDM JAB 2016, 306 (Summary of 2014 and 2015 Cigarette Market Surveys), RDM JAB 2016, 281 (Summary of 2014 and 2015 Smokeless Market Surveys) and LSI 2016 097 (Characterization of Tobacco-Minor Alkaloids) were omitted from the MRTPAs in question. These datasets and associated define files are provided as itemized in Table 1.

Table 1. Index of RJRT Chemistry Studies in Question

Reference	Title	Appended Files
RDM JAB 2016, 306	Summary of 2014 and 2015 Cigarette Market Surveys	q01a-cigarette-market-survey
RDM JAB 2016, 281	Summary of 2014 and 2015 Smokeless Market Surveys	q01a-smokeless-market-survey
LSI 2016 097	Characterization of Tobacco-Minor Alkaloids	q01a-minoralkaloids

- b. Statistical programming code used to produce the results for study LSI 2016 097, discussed in Section 7_1**

Provide these documents for each study. If you have already provided this information, indicate the exact location within your MRTPAs.

RAIS RESPONSE

RAIS has reviewed the datasets provided by the contract research organization who conducted the study LSI 2016 097 (Characterization of Tobacco-Minor Alkaloids) and determined that statistical analysis of the datasets were conducted via Microsoft Excel spreadsheet functions. These functions include average [e.g., =AVERAGE(C8:C10)], standard deviation [e.g., =STDEV(C8:C10)], lower confidence interval [e.g., =IF(C12-(TINV(0.05,3-1)*(C13/SQRT(3)))>0,C12-(TINV(0.05,3-1)*(C13/SQRT(3))),0)], and upper confidence interval [e.g., =C12+(TINV(0.05,3-1)*(C13/SQRT(3)))]. Consequently, no statistical programming code is available to provide.