



RAI Services Company

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August 21, 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 4) 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 Four (4) 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 end.

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

FDA-Listed Deficiencies and RAIS Response

4. *All of your MRTPAs provide data from the Covance Clinical Study Report (No. 6270-229, pdf document entitled “1 to 13_7.pdf”) and reference protocol amendment 6 (section 16_1_1_14) in Section 7.4, folder “01_HSD0702_QOL.” Protocol amendment 6 added an exit interview questionnaire administered at week 24 and at early withdrawal for groups A, B (switched to Snus), and C (Table 9-1, p. 75 of the Clinical Study Report). Section 9.5.10 (p. 59, PDF p. 87 of the Clinical Study Report) states “The exit interview questionnaires were presented in the protocol and these results have been summarized separately by the Sponsor.” Section 13.6 (p. 308, PDF p. 336 of the Clinical Study Report) states that “an overall summary of much of this learning is beyond the scope of this clinical study report and various elements have been and will be summarized elsewhere.” We have not identified data from the exit interviews. These data would be important for assessment of how consumers actually use the snus product in the natural environment. Provide the data for this study or, if you have already provided this information, indicate the exact location within your MRPTAs.*

RAIS RESPONSE

The exit interview data referenced in Item Four (4) was a post-hoc analysis compiled by a marketing research firm, rather than a component of the clinical study report prepared by the clinical research organization responsible for the study conduct. As such, RAIS understood the exit interview questionnaires and associated data to be beyond the scope of the study findings. As FDA now states “[t]hese data would be important for assessment of how consumers actually use the snus product in the natural environment,” the requested information; including questionnaires, datasets, and the associated define file; are provided as itemized in Table 1.

Table 1. Exit Interview Documentation Relevant to HSD 0702/CSR No. 6270-229

Description	Appended Files	
Snus Subject Group	q04-hsd0702-exit-qol-questionnaire-ver-06-snus	q04-qol-exit-interview
Tobacco Heating Product Subject Group	q04-hsd0702-exit-qol-questionnaire-ver-06-tobacco-heating	
Tobacco Burning Product Subject Group	q04-hsd0702-exit-qol-questionnaire-ver-06-tobacco-burning	