



RAI Services Company

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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 6) 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 Six (6) 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

6. *All of your MRTPAs refer to the following clinical studies of Camel Snus products in Section 7.4, but we were unable to locate the study protocols:*

- a. *Folder “05\_CSD0905\_SL” contains the Clinical Study Report referring to the missing experimental protocols HRRC proposal #0905 and #0905A (p. 5 of “csd0905 report.pdf.”)*
- b. *Folder “06\_CSD0914\_SUL” contains the Clinical Study Report referring to the missing experimental protocol HRRC proposal #0906 (p. 5 of “csd0914 single unit final report.pdf”)*

*If you have already provided this information, indicate the exact location within your MRTPAs. Otherwise, submit the missing protocols and any amendments to those protocols.*

RAIS RESPONSE

Experimental protocols for clinical studies CSD0905 and CSD0914 are provided as itemized in Table 1. Please note that protocols pursuant to CSD0905 were incorrectly titled “HRRC proposal #0905 and #0905A”.<sup>2</sup> This error originated from the associated RJRT internal report RDR EKR 2010, 348. The appended protocol includes the correct HRRC proposal number.

For study CSD0914, two protocol amendments are also provided in Table 1. Two modifications to the original study protocol occurred and were documented as individual amendments. No final amended protocol which incorporates these modifications exists.

**Table 1. Index of RJRT Clinical Studies in Question**

Clinical Study	Description	Appended Files
CSD0905	Snus Local	<a href="#">q06a-HRRC_PROPOSAL_num0902A_final</a>
CSD0914	Single Unit Local	<a href="#">q06b-csd0914-protocol</a> <a href="#">q06b-amendment1-0906</a> <a href="#">q06b-amendment2-0906</a>

<sup>2</sup> For clarity, both the CSD numbering system and the HRRC numbering system used similar formats (last 2 digits of year + 2 digit numerical sequence) but they were neither intended to be, nor were they coincident (except by happenstance). Thus, the study CSD0905 corresponds to HRRC #0902 and HRRC #0902A. As the final CSD0905 study protocol was reflected in HRRC proposal #0902A, only this final protocol version is relevant and is being provided herein.