



RAI Services Company

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September 28, 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 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.

Items One (1), Two (2), Four (4), Five (5), Six (6), Seven (7), Eight (8), Ten (10), and Eleven (11) were addressed in previous responses.<sup>2</sup> Items Three (3) and Nine (9) will be addressed in a subsequent response and will utilize file formats compatible with the eSubmitter tool. RAIS has made every effort to address as many items as possible within these responses and, as discussed previously with FDA<sup>3</sup>, will communicate a timeframe for completion of responses to outstanding items as rapidly as that information becomes available.

This partial response addresses CTP's eSubmitter compatibility issues with text (.txt) and Microsoft Excel (.xlsx) file formats.<sup>4</sup> RAIS has produced the document [Summary of File Replacements](#) which details the affected files from the aforementioned responses and appends compatible versions of these files.

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,



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

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<sup>2</sup> See RAIS' August 24, 2017 response to FDA's July 25, 2017 ADVICE/INFORMATION REQUEST addressing Items One (1), Two (2), Four (4), Five (5), Six (6), and Ten (10) and RAIS' September 15, 2017 response to FDA's July 25, 2017 ADVICE/INFORMATION REQUEST addressing Items Seven (7), Eight (8), and Eleven (11).

<sup>3</sup> A discussion of anticipated timing for RAIS' response to FDA's July 25, 2017, ADVICE/INFORMATION REQUEST letter occurred during an August 1, 2017 teleconference initiated by Ms. Jennifer Schmitz of FDA. Dr. Michael Borgerding participated in the call on behalf of RAIS. Dr. Benjamin Apelberg and others from FDA also participated in the call.

<sup>4</sup> A discussion regarding issues with transmission of text (.txt) and Microsoft Excel (.xlsx) file formats occurred during a September 26, 2017 teleconference initiated by Ms. Jennifer Schmitz of FDA. Dr. Michael Borgerding participated in the call on behalf of RAIS. It was agreed that .txt files would be converted to .pdf and .xlsx files would be converted to .xls.