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December 3, 2018

Hans Rosenfeldt, Ph.D.
Deputy Director, Division of Nonclinical Science
Deirdre Kittner, Ph.D., MPH
Deputy Director, Division of Population Health Science
Office of 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 (DEFICIENCY 23) to AUGUST 10, 2018 ADVICE/INFORMATION REQUEST for PM0000427-PM0000432 and MR0000068-MR0000073

Dear Drs. Rosenfeldt and Kittner:

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") August 10, 2018, ADVICE/INFORMATION REQUEST letter regarding RAIS's submission of Premarket Tobacco Applications ("PMTAs") and Applications Seeking a Modified Risk Tobacco Product Order ("MRTP Applications"), submitted under Section 910(b) and Section 911(d) of the Food, Drug, and Cosmetic Act ("FDCA"), respectively, on March 30, 2017 for the following tobacco products:

- PM0000427/MR0000072, Camel Snus Robust
- PM0000428/MR0000070, Camel Snus Mellow

[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"), and R.J. Reynolds Vapor Company ("RJRV"). References to RAIS in this letter refer to itself and RJRT where applicable.

- PM0000429/MR0000069, Camel Snus Frost Large
- PM0000430/MR0000071, Camel Snus Mint
- PM0000431/MR0000073, Camel Snus Winterchill
- PM0000432/MR0000068, Camel Snus Frost

This response refers to Deficiency Twenty-Three (23) in the aforementioned ADVICE/INFORMATION REQUEST. Deficiencies not addressed in this submission will be covered in separate responses. In this response, we have repeated CTP's requests, verbatim and in bold italics, followed by RAIS's 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,

P.P.

Michael W. Ogden, Ph.D.
Senior Vice President
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RAI Services Company

FDA-Listed Deficiencies and RAIS Response

23. In Section 9.4.2 "Adverse Events," (Folder 9, "Proposed Post-Market Surveillance Program For Camel Snus Products Under A Modified Risk Tobacco Product Order") you briefly summarize the Camel Snus historical consumer complaint experience: "… complaints related to Camel Snus are currently rare. When they do occur, they are more likely to be complaints related to freshness or other product characteristics versus complaints about physical effects from the product." Camel snus products have been on the U.S. market since 2006 (Caraway and Chen, 2013). We cannot locate submission data which summarize the consumer health effect complaints associated with Camel snus products during the time they have been marketed. Submit a tabular summary (such as line listing of data) describing the existing consumer health effect complaints associated with use of Camel Snus. FDA needs this information in order to evaluate the health effects of the six Camel Snus products that are the subject of these applications in users and nonusers. If you have already provided this information, indicate its exact location within your applications.

RAIS RESPONSE TO DEFICIENCY 23

RAIS understands FDA's Deficiency 23 as a request to provide summary data of the existing consumer health effect complaints associated with use of Camel Snus. (b) (4)

(b) (4)

RJRT has a validated system used to log, manage, and report complaints. This system was implemented for official complaint documentation in August 2012. RJRT has collected Camel Snus complaint data from 2012-2018 that is reflective of the six Camel Snus styles subject of the MRTPAs/PMTAs. RAIS provides the Camel Snus health effect complaint data in d23-rjrt-snus-complaint-summary and a summary of these complaints in Table 1. (b) (4)

(b) (4)

Table 1. Summary of Camel Snus Health Effect Complaints (August 2012 - July 2018)							
Count of Complaints							
Complaint Category	**2012***	**2013**	**2014**	**2015**	**2016**	**2017**	**2018***
(b) (4)							