RAI Services Company

Michael W. Ogden, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
Winston-Salem, NC 27101
336-741-5787
Fax: 336-728-7675
ogdenm@rjrt.com

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October 18, 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 1) 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 One (1) 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,

Michael W. Ogden, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs
RAI Services Company

1. ***All of your MRTPAs/PMTAs provide information on the design parameters for the new products. However, you do not include all of the design parameters needed to fully characterize the products. In order for FDA to adequately characterize and evaluate the products, it is necessary to evaluate certain design parameters that are distinctive to the products subject of these MRTPAs/PMTAs. Provide the target specification for the following design parameters for each new product:***

    a. ***Pouch material air permeability (CU)***

    Provide the upper and lower range limits for the following design parameters for each new product:

    b. ***Pouch material air permeability (CU)***

    c. ***Tobacco cut size (mm)***

    For tobacco cut size range limits, alternatively, you may provide the detailed, step-by-step information about the cutting and sieving manufacturing processes and all relevant process parameters, including but not limited to the specific cutter size settings, number of times the tobacco is cut, cutter and screen specification and range limits/tolerances, cutting equipment used, sieving equipment used, sieving specifications and tobacco moisture content.

RAIS RESPONSE TO DEFICIENCY 1a

RAIS understands FDA's request to be for target specifications for pouch material air permeability (CU) for the Camel Snus products.

RAIS notes that FDA has requested air permeability (CU). However, CORESTA Units (CU) are typically used to characterize cigarette papers, and as such may not be appropriate to characterize other materials.[1] Additionally, RJRT does not use paper to produce the portioned unit of snus, but instead uses a material referred to as "fleece." Fleece is a dry laid nonwoven material made from viscose fiber; it is not a traditional cellulose paper. Typically, the nonwoven industry measures air permeability ($L/m^2/sec$) as opposed to porosity in CORESTA Units.[2] As such, all information presented here will be [redacted]

[1] The CORESTA Unit (CU), Accessed via https://www.coresta.org/coresta-unit-cu
[2] EDANA, Accessed via https://edana.org/

[redacted]

RAIS RESPONSE TO DEFICIENCY 1b

RAIS understands FDA's request to be for upper and lower range limits for air permeability (CU) for the Camel Snus products.

[redacted]

[redacted]

RAIS RESPONSE TO DEFICIENCY 1c

RAIS understands FDA's request to be for the upper and lower limits for tobacco cut size (mm) for the Camel Snus products. [redacted] to satisfy FDA's request, RAIS will provide a description of the manufacturing process for Camel Snus tobaccos subject to this submission.

[redacted]

[redacted]

[redacted]