



RAI Services Company

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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 2) 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 Two (2) 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,



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RAI Services Company

2. *All of your MRTPAs/PMTAs include design parameter specifications but do not include data confirming that the target specifications are met. In order to confirm the target specifications are met, provide the test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for all of the following design parameters for each new product:*

- a. Tobacco cut size (mm)*
- b. Portion mass (mg)*
- c. Final pouch moisture (%)*
- d. pH*
- e. Pouch material air permeability (CU)*

For tobacco cut size, if manufacturing process information is submitted in response to issue #1 above, you may satisfy this requirement by providing the tobacco particle size distribution.

For each of the above parameters, provide the necessary data on a per unit of measurement of product basis (e.g., portion mass should be reported in milligrams per portion).

Certificates of analysis (COAs) from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, ensure that the COAs include a target specification, quantitative acceptance criteria, parameter units, test data average value, and the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

RAIS RESPONSE TO DEFICIENCY 2a

RAIS understands FDA's request to be data to support that tobacco cut size target specifications are met during the manufacturing of the Camel Snus products subject of this submission. (b) (4)

(b) (4)

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(b) (4)



Complete data sets (including number of replicates, standard deviations, and time between manufacturing and analysis) are provided in [d02a-particle-size-complete-data-set](#).

¹ ASTM International. Designation: E11-17. Standard Specification for Woven Wire Test Sieve Cloth and Test Sieves. Table 1: Nominal Dimensions and Permissible Variations for Sieve Cloth and Compliance, Inspection and Calibration Test Sieves. Accessed July 24, 2017 with no further reproduction authorized. Copyright law requires permission from ASTM International prior to further distribution.

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(b) (4)



Testing laboratory and accreditation(s)

RJRT currently has an outsourced solution for analytical testing using a Professional Staffing Services (PSS) model that is provided by Eurofins Lancaster Laboratories Professional Scientific Services (ELLPSS). The laboratory facility is on-site at RJRT and the laboratory equipment and testing protocols are developed and/or maintained by RJRT. Operation of the facility and testing is conducted by ELLPSS personnel on a contract basis. The certificates of ISO 17025 accreditation list R.J. Reynolds Tobacco Company as the accredited facility, and ELLPSS is contractually required to maintain the Quality System and ensure accreditation while providing analytical services. The RJRT (2010-2018) Chemical and Mechanical accreditations are attached as [d02a-chemical-mechanical-lab-accreditations](#).

Quantitative test protocols and method used

(b) (4)



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(b) (4)

(b) (4)

RAIS RESPONSE TO DEFICIENCY 2b

RAIS understands FDA's request to be for portion mass (mg) test data verifying that products meet specifications at the time of manufacturing. Representative raw data, as collected at the time of manufacture for individual pouch weight, are located in appendices listed in Table 3 for all Camel Snus products relevant to this amendment. (b) (4)

(b) (4)

Table 3: Location of Individual Pouch Mass (mg) Test Data	
Product	Location(s)
Camel Snus Robust	d02b-portion-wt-test-data-camel-snus-robust
Camel Snus Mellow	d02b-portion-wt-test-data-camel-snus-mellow
Camel Snus Frost Large	d02b-portion-wt-test-data-camel-snus-frost-large
Camel Snus Mint	d02b-portion-wt-test-data-camel-snus-mint
Camel Snus Winterchill	d02b-portion-wt-test-data-camel-snus-winterchill
Camel Snus Frost	d02b-portion-wt-test-data-camel-snus-frost

(b) (4)

(b) (4)

(b) (4)

² See November 22, 2017 letter from James N. Figlar, Ph.D. to Hans Rosenfeldt, Ph.D. "Re: Response to November 3, 2017 Information Request for PM0000427-PM0000432."

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(b) (4)

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(b) (4)

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RAIS RESPONSE TO DEFICIENCY 2c

RAIS understands FDA's request to be for moisture test data verifying that products meet specifications at the time of manufacture. Representative raw data, as collected at the time of manufacture for the Camel Snus products relevant to this amendment, are located in appendices listed in Table 5. (b) (4)

(b) (4)

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Table 5: Location of Moisture Test Data	
Product	Location(s)
Camel Snus Robust	d02c-moisture-ph-test-data-camel-snus-robust
Camel Snus Mellow	d02c-moisture-ph-test-data-camel-snus-mellow
Camel Snus Frost Large	d02c-moisture-ph-test-data-camel-snus-frost-large
Camel Snus Mint	d02c-moisture-ph-test-data-camel-snus-mint
Camel Snus Winterchill	d02c-moisture-ph-test-data-camel-snus-winterchill
Camel Snus Frost	d02c-moisture-ph-test-data-camel-snus-frost

(b) (4)

(b) (4)

RAIS RESPONSE TO DEFICIENCY 2d

RAIS understands FDA's request to be for pH test data verifying that products meet specifications at the time of manufacture. Representative raw data, as collected at the time of manufacture for the Camel Snus products relevant to this amendment are located in appendices listed in Table 7 (b) (4)

(b) (4)

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Table 7: Location of pH Test Data	
Product	Location(s)
Camel Snus Robust	d02c-moisture-ph-test-data-camel-snus-robust
Camel Snus Mellow	d02c-moisture-ph-test-data-camel-snus-mellow
Camel Snus Frost Large	d02c-moisture-ph-test-data-camel-snus-frost-large
Camel Snus Mint	d02c-moisture-ph-test-data-camel-snus-mint
Camel Snus Winterchill	d02c-moisture-ph-test-data-camel-snus-winterchill
Camel Snus Frost	d02c-moisture-ph-test-data-camel-snus-frost

(b) (4)

(b) (4)

RAIS RESPONSE TO DEFICIENCY 2e

RAIS understands FDA's request to be for air permeability test data for the fleece (pouch material) used in the Camel Snus products.

(b) (4)

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(b) (4)



³ EDANA, Accessed via <https://edana.org/>

⁴ This method may also be referenced as ISO method 9073-15:2007, Textiles—Test methods for nonwovens—Part 15: Determination of air permeability.

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