



RAI Services Company

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CONFIDENTIAL, NOT FOR PUBLIC DISCLOSURE

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 4) 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 Four (4) 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

4. All of your MRTPAs/PMTAs provide information about (b) (4) and (b) (4) as types of tobacco used in the tobacco blend (Section 3.2.1.4). (b) (4)



To fully characterize the composition of the new tobacco products, clarify the tobacco blend and quantities of each tobacco blend type present in the new products. Provide uniquely identifying information for all tobacco (e.g., grades used, tobacco grading system) and information on constituents and other properties that distinguishes between the different types of tobacco.

RAIS RESPONSE TO DEFICIENCY 4

RAIS understands FDA's request to be for information regarding the tobacco grade components, tobacco grading system, tobacco blend, and quantities of tobacco types used in Camel Snus. RAIS notes that information regarding the tobacco blend and quantities of tobacco type was previously provided in Section 3.2.1.3.2 for these products. It is important to note that in all Camel Snus products, as described in Section 3.2.3.1 of the MRTP application and October 4, 2017 and June 13, 2018 amendments, the (b) (4). This (b) (4)

(b) (4) is common across all product styles.

(b) (4)



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[REDACTED]

[REDACTED]

[REDACTED]

Table 1: Tobacco Grade Comparison		
Leaf Type/Form	Leaf Grades	Country of Origin
(b) (4)		

[REDACTED]

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(b) (4)

(b) (4)

Tobacco blend components are summarized in the tables below.

Table 2: Camel Snus Frost Tobacco Blend Ingredients

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
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(b) (4)

Table 3: Camel Snus Mint Tobacco Blend Ingredients

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
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(b) (4)

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Table 4: Camel Snus Mellow Tobacco Blend Ingredients

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
(b) (4)				

Table 5: Camel Snus Frost Large Tobacco Blend Ingredient

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
(b) (4)				

Table 6: Camel Snus Winterchill Tobacco Blend Ingredients

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
(b) (4)				

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Table 7: Camel Snus Robust Tobacco Blend Ingredients

Ingredient Name	Tobacco Product Single Quantity	Tobacco Product Minimum Quantity	Tobacco Product Maximum Quantity	Unit of Measure
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(b) (4)

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PM0000427- PM0000432/MR0000068-MR0000073 A/I PARTIAL RESPONSE – DEFICIENCY 4