



RAI Services Company

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**CONFIDENTIAL, NOT FOR PUBLIC DISCLOSURE**

March 21, 2018

Jennifer Schmitz, MPH  
Regulatory Health Project Manager  
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: AMENDMENT TO MODIFIED RISK TOBACCO PRODUCT APPLICATIONS for MR0000068-MR0000073**

Dear Ms. Schmitz:

RAI Services Company ("RAIS")<sup>1</sup>, on behalf of R.J. Reynolds Tobacco ("RJRT"), submits the following amendment to Applications Seeking a Modified Risk Tobacco Product Order ("MRTP Applications"), submitted under Section 911(d) of the Food, Drug, and Cosmetic Act ("FD&C Act") 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> RAIS is a wholly owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for regulatory compliance for RAI's operating companies, including R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Company, LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("SFNTC") and R.J. Reynolds Vapor Company ("RJR"). References to RAIS in this letter include itself and RJRT, where applicable.

During a recent internal review of the aforementioned MRTPAs, RAIS discovered several transcription errors within Sections 3.1 through 3.2. RAIS would like to correct the record as it relates to these errors. As seen in Appendix A, RAIS has itemized these discrepancies by page number, noted the erroneous information, and provided the corrected values or text. In instances where text has been amended, these changes are noted in bold italics. RAIS has also updated three (3) figures to better reflect the quality inspection aspects of the Camel Snus manufacturing processes (see Appendix B). These figures are numbered and titled as they appeared in the MRTPAs and supersede, in whole, the previous figures. Additionally, clerical errors identified in a supplier CoA (*described as (b) (4) (b) (4) COA" under Representative Manufacturer Information in Table 3.2-29 of the original March 30, 2017 submissions*) have been corrected by the supplier and a revised CoA is provided in Appendix C. Please advise should FDA prefer a revised version of the affected sections.

Please note that the enclosed response does contain confidential commercial and non-public trade secret information belonging to RAIS, RJRT, or RJRT's vendors. As such, RAIS is providing both an original version of this amendment and a redacted version for posting to the public docket.

All such confidential and trade secret information is exempt from public disclosure under § 301(j) and § 906(c) of the FD&C Act, 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

**APPENDIX A**

<b>Page Number</b>	<b>Table</b>	<b>Subject Product(s)</b>	<b>Field</b>	<b>Stated Information</b>	<b>Amended Information</b>
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(b) (4)



Page Number	Table	Subject Product(s)	Field	Stated Information	Amended Information
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(b) (4)



**APPENDIX B**

**Figure 3.2-5: Manufacture of (b) (4)**

(b) (4)



**Figure 3.2-7: Pouching and Packing of Camel Snus Products on Merz Maker**



**Figure 3.2-8: Pouching and Packing of Camel Snus Products on GD Maker**

(b) (4)



**APPENDIX C**

(b) (4)



**CERTIFICATE OF ANALYSIS**

(b) (4)



We guarantee the product conforms to the parameter of the published product specification, details of which are given above.

No deviations from stated test methods occurred.

This document provides confirmation that the formulation to produce the material is identical to the RJRT Product Integrity formulation disclosure of record.