



RAI Services Company

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

CONFIDENTIAL, NOT FOR PUBLIC DISCLOSURE

July 23, 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")¹, 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 ("FDCA") 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).

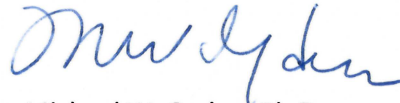
¹ RAIS is a wholly owned subsidiary of Reynolds American Inc. ("RAI") that bears primary responsibility for regulatory compliance for RAI's operating companies, including R.J. Reynolds Tobacco Company ("RJRT"), American Snuff Company, LLC ("ASC"), Santa Fe Natural Tobacco Company, Inc. ("SFNTC") and R.J. Reynolds Vapor Company ("RJRV"). References to RAIS in this letter include itself and RJRT, where applicable.

This amendment addresses four topics which were surfaced, in three instances, during FDA's May 22, 2018 inspection of RJRT and American Snuff Company ("ASC") in relation to the aforementioned MRTPAs.

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

AMENDMENT

Likelihood of Use and Population Modeling – Execution 1

RAIS recently identified a number of minor data transcription errors within one of the study reports submitted in support of the aforementioned MRTPAs.

Specifically, for the document titled “Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-users – *First Execution of Consumer Testing* – Amended Final Report” dated October 4, 2016, *Appendix Table A-13* was found to have transcription errors for a number of the projected purchase rates for ‘current regular cigarette users not likely to quit tobacco use’ specific to the ‘test arm’, or those viewing the modified-risk advertisement.² A revised copy of this report which includes the corrected *Appendix Table A-13* is provided herein as [Amended Final Report-LOU-Execution 1-Oct 2016-Amended Table A-13](#).

These estimates for projected purchase are not formally discussed within the corresponding ‘likelihood of use’ report, but instead serve as source data for subsequent statistical modeling, i.e., where age-interval-specific projections are needed. While the transcription errors only change the projected purchase rates by roughly a percentage point, the statistical modeling provided in support of advertising execution 1 was repeated based on the slightly modified rates.

Therefore, a revised final report for the statistical modeling conducted in support of advertising execution 1 is provided herein as [Assessing the Population Health Effects of Camel SNUS and its Proposed Marketing as a Modified-Risk Tobacco Product: Statistical Modeling Using the Dynamic Population Modeler - Execution 1 Final Report: Revised](#). This updated final report also includes updated Appendices A, C, D, E, G and H, specific to the modeling for advertising execution 1. Appendices B and F are re-submitted without modification. Detailed change logs are provided at the beginning of the revised final report and each of the updated appendices.

Camel Snus Ingredients – Chemical and Physical Properties

RAIS recently identified discrepancies between Sections 3.2.1.5.2-3.2.1.5.3 and RJRT’s system of record regarding a limited number of chemical and physical properties for ingredients utilized in Camel Snus. These instances include (b) (4)

(b) (4) . Additionally, (b) (4) tables for (b) (4) and the (b) (4) used in several styles of Camel Snus were not

² *Table A-13: Weighted Mean Modeled Purchase Rate, Test versus Control Camel SNUS Advertising Materials among Current Regular Cigarette Users by Intent*, from the October 4, 2016 report titled, “Camel SNUS Modified Risk Messaging: Likelihood of Use among Tobacco Users and Non-Users, First Execution of Consumer Testing, Amended Final Report”, page 83.

included in the original submissions. Revised tables are provided herein as [Sections 3.2.1.5.2-3.2.1.5.3 – Amended](#) and should supersede, in whole, said sections of the original MRTPAs. A redacted version of these tables is also provided as [Sections 3.2.1.5.2-3.2.1.5.3 – Amended \(Redacted\)](#).

2014 and 2015 Market Surveys of U.S. Cigarettes and Smokeless Tobacco Products

Sections 6.1.5.4.3-6.1.5.4.4 of the MRTPAs reference two RJRT chemistry reports:

- 2014 and 2015 market surveys of U.S. cigarette mainstream smoke yields (RDM JAB 2016, 306); and
- 2014 and 2015 market surveys of U.S. smokeless tobacco products (RDM JAB 2016, 281).

(b) (4)



(b) (4)



Camel Snus Stability Study

RAIS takes this opportunity to supplement the record with a recently completed stability study conducted by RJRT. (b) (4)

(b) (4)

The final study report, including the study protocol, statistical analysis plan, replicate data for all analyses, statistical analyses, methods of analysis, product batch records, sample chain of custody, and laboratory accreditations are provided herein as [RDM TRM 2018, 192](#). A redacted version of the final study report is provided as [RDM TRM 2018, 192 \(Redacted\)](#). Datasets and associated define files are provided as itemized in Table 2.

Table 2. Index of Stability Study Datasets

Study Report	Appended Files
RDM TRM 2018, 192	Camel Snus Frost
	Camel Snus Frost Large
	Camel Snus Mellow
	Camel Snus Mint
	Camel Snus Robust
	Camel Snus Winterchill