

## **Temporary Compliance Waiver Notice**

The linked files may not be fully accessible to readers using assistive technology. We regret any inconvenience that this may cause our readers. In the event you are unable to read the documents or portions thereof, please email [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov) or call 1-877-287-1373.



**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**

September 14, 2020

Deirdre L. Kittner, Ph.D., M.P.H.  
Deputy Director  
Office of Science  
Center for Tobacco Products  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Re: TIMING TO RESPOND TO SEPTEMBER 1, 2020 DEFICIENCY LETTER FOR MR0000068-MR0000073**

Dear Dr. Kittner:

On September 1, 2020, the United States Food and Drug Administration's Center for Tobacco Products ("CTP") issued a Deficiency Letter regarding Modified Risk Tobacco Product Applications ("MRTPAs") submitted under Section 911(d) of the Food, Drug, and Cosmetic Act ("FDCA") by RAI Services Company ("RAIS"),<sup>1</sup> on behalf of R.J. Reynolds Tobacco Company ("RJRT"), on March 30, 2017 for the following products:

- MR0000068, Camel Snus Frost
- MR0000069, Camel Snus Frost Large
- MR0000070, Camel Snus Mellow
- MR0000071, Camel Snus Mint
- MR0000072, Camel Snus Robust
- MR0000073, Camel Snus Winterchill

In its September 1, 2020 Deficiency Letter, FDA requests that "within 14 calendar days from the date of this letter, [RAIS] inform [FDA] of how much time [RAIS] need[s] to provide a complete response to all deficiencies." As described in more detail below, RAIS takes this opportunity to inform FDA that it believes that (b) (4) is needed to provide a complete response to FDA's September 1, 2020 Deficiency Letter. Importantly, RAIS intends to provide all information that FDA states is necessary for FDA to

---

<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 ("RJRV"). References to RAIS in this letter include itself and RJRT, where applicable.

make a scientific determination regarding the MRTPAs for Camel Snus. Further, RAIS intends to provide the information in a manner fully consistent with the scope and content indicated by FDA in Deficiencies 1-3. The stated timeframe to respond to FDA's Deficiencies 1-3 (b)(4)

[Redacted]

Below, for FDA's review and consideration, are the types of information RAIS contemplates providing in its response to FDA's September 1, 2020 letter and a detailed plan, including the timeframe it believes is necessary to provide a complete response to FDA.

(b) (4)

(b) (4)

RAIS welcomes this opportunity to satisfy the remaining concerns noted by FDA for these MRTPAs and fully intends to continue to engage with the Agency to understand its concerns and to generate the appropriate evidence to demonstrate that MR0000068-MR0000073 support a positive scientific determination.

This letter contains 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 Food, Drug, and Cosmetic Act ("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,

DocuSigned by:  
*Michael W. Ogden*  
145E09081AB6417...

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

MOST CONFIDENTIAL INFORMATION  
R.J. Reynolds Tobacco Company – Timing to Response for Deficiency Letter  
MR0000068-MR0000073