

Temporary Compliance Waiver Notice

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Paige C. Magness
Senior Vice President
Regulatory Affairs

September 29, 2021

Sent Via CTP Portal

Food and Drug Administration
Office of Science
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Response to Deficiency Letter for MR0000108, dated March 26, 2021

Dear Sir/Madam:

Altria Client Services LLC ("ALCS"), on behalf of U.S. Smokeless Tobacco Company LLC (USSTC),¹ submits the attached responses to the deficiency letter dated March 26, 2021, for MR0000108.

These responses contain trade secret and confidential commercial information that USSTC considers to be proprietary and highly sensitive, and which is protected from disclosure under FDCA §§ 301(j) and 906(c) (21 U.S.C. §§ 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. § 1905), the Freedom of Information Act ("FOIA") (5 U.S.C. § 552), and FDA's implementing regulations, 21 C.F.R. Part 20. If FDA receives a request for these records and tentatively determines that any portion of the submission is disclosable, USSTC requests that FDA provide notice and an opportunity for USSTC to object to any disclosure in accordance with 21 C.F.R. §§ 20.47 and 20.61. USSTC reserves all legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

¹ USSTC is a wholly-owned subsidiary of Altria Group, Inc. (Altria). ALCS provides certain services, including regulatory affairs, research and development, and regulatory sciences to the Altria family of companies. "We" or similar pronouns are used throughout to refer to USSTC.

TRADE SECRET/CONFIDENTIAL COMMERCIAL INFORMATION

Altria Client Services LLC
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(b) (6)

The authorized contact for this response is:

Ms. Rebecca A. Rivas, RAC
Sr. Director, Regulatory Submissions
Altria Client Services LLC
601 E. Jackson Street
Richmond, VA 23219
Telephone: (b) (6)
Email: (b) (6)

Sincerely,

(b) (6)

Attachments