



Rebecca A. Rivas
Senior Director,
Regulatory Submissions

July 11, 2018

Via CTP Portal

Ms. Ebony Jackson
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Amendment to MR0000108 - Modified Risk Tobacco Product Application - U.S. Smokeless Tobacco Company LLC – Copenhagen® Snuff Fine Cut

Dear Ms. Jackson:

Per our discussion, Altria Client Services LLC (“ALCS”), on behalf of the manufacturer U.S. Smokeless Tobacco Company LLC (“USSTC”)¹, submits the attached amendment to the Modified Risk Tobacco Product Application (“MRTPA”) MR0000108 submitted to CTP on March 20, 2018.

Per my discussion with Jennifer German on June 11, 2018, in which we were notified that CTP is requesting a tabulated index for the published literature in the MRTPA, we provide in this amendment a Tabulated Master Bibliography Index for MRTPA MR0000108.

This amendment to the MRTPA contains 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”). Altria Client Services LLC, provides certain services, including regulatory affairs, research and development, and health sciences to the Altria family of companies. “We” or similar pronouns are used throughout to refer to USSTC.

CONFIDENTIAL COMMERCIAL INFORMATION

Altria Client Services LLC
2325 Bells Road
Richmond, Virginia 23234
(804) 335-2853
Rebecca.A.Rivas@altria.com

Please contact me should you have any questions regarding this amendment.

With best regards,

A handwritten signature in cursive script, reading "Rebecca A. Rivas". The signature is written in black ink and is positioned above the printed name.

Rebecca A. Rivas