Altria
Altria Client Services

Jose Luis Murillo
Vice President
Regulatory Affairs

March 20, 2018

Via Electronic Media

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

Dear Sir / Madam:

Altria Client Services LLC ("ALCS"), on behalf of the manufacturer U.S. Smokeless Tobacco Company LLC ("USSTC")[1], submits the enclosed Modified Risk Tobacco Product Application ("MRTPA") pursuant to Section 911 of the Federal Food, Drug, and Cosmetic Act (the "FDCA").

USSTC is seeking a risk modification order under Section 911(g)(1) of the FDCA for the grandfather product Copenhagen® Snuff Fine Cut (GF1200194). USSTC requests that FDA designate the candidate product, Copenhagen® Snuff Fine Cut, as a modified risk tobacco product and permit marketing of the candidate product with the following proposed modified risk claim, as provided in the proposed advertising and labeling:

> "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

Copenhagen® Snuff Fine Cut (GF1200194) was commercially marketed in the United States as of February 15, 2007. As such, Copenhagen® Snuff Fine Cut (GF1200194) is not a new tobacco

[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.

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product, as defined by FDCA Section 910(a) (1), and does not require premarket review and authorization.

A copy of the MRTPA with transparent highlights of proposed redactions will be submitted to the Center for Tobacco Products, Freedom of Information Office, within the next 30 days.

The following table provides product identification information for Copenhagen® Snuff Fine Cut (GF1200194):

Information Type	GF1200194 Product Information
Universal Product Code (UPC)	0-731071-91
Brand / Subbrand	Copenhagen® Snuff Fine Cut
Manufacturer	U. S. Smokeless Tobacco Company
Tobacco Product Category	Moist Snuff
Subcategory	Loose non-portioned
Tobacco Cut	Fine Cut
Package Type	Fiberboard Can/Metal Lid
Package Size	34.02 grams
Identifying Flavor[2]	None

[2] CTP has not issued an explanation of what it considers to be a "characterizing flavor" or how it expects manufacturers to determine whether a particular smokeless tobacco product has a "characterizing flavor." Therefore, we use the term "Identifying Flavor" to indicate whether USSTC identifies the product by use of a flavor identifier, or whether USSTC does not use a flavor identifier to identify the product (i.e., None).

The following table provides information on previous submissions for the grandfather product Copenhagen® Snuff Fine Cut (GF1200194):

Submission Type	Date of Submission
Grandfather Determination Submission	July 9, 2012 Determination received November 1, 2012
HPHC Report	May 16, 2017
Ingredient Report	July 21, 2017

The following table provides information on meetings with CTP associated with the MRTPA for the grandfather product Copenhagen® Snuff Fine Cut (GF1200194):

Meeting Type	Meeting Date
Pre –submission Meeting -TC0002755	December 7, 2017
Analyses of mortality outcomes -TC0002431	August 2, 2017

The Grandfather Product Copenhagen® Snuff Fine Cut is in compliance with the requirements of the Act, specifically:

- Section 904(a)(3) - A Harmful and Potentially Harmful Constituents report was submitted at least 90 days prior to the new product entering commercial distribution.
- Sections 904(a)(1), 904(c)(2) and 904(c)(3) - An ingredient report was submitted and, if required, a change report will be submitted, at least 90 days prior to the product entering commercial distribution.
- Section 905(b) - An annual establishment registration has been submitted for USSTC.
- Section 905(i) - A product listing has been submitted for USSTC.
- Section 907(a)(1)(B) - There are no federal laws establishing tolerance limits for pesticide chemical residues that apply to domestically grown tobacco.

This MRTPA contains 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.

The authorized contact for this submission is:

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Sincerely,