



Background: Altria Client Services LLC (“ALCS”) on behalf of U.S. Smokeless Tobacco Company LLC (“USSTC”) Modified Risk Tobacco Product Application

On March 20, 2018, Altria Client Services LLC (“ALCS”) on behalf of U.S. Smokeless Tobacco Company LLC (“USSTC”) submitted a Modified Risk Tobacco Product Application (“MRTPA”) seeking a risk modification order under Section 911(g)(1) of the Federal Food, Drug and Cosmetic Act (FD&C Act). The FD&C Act requires Food and Drug Administration (FDA) to make MRTPAs available to the public for review and comment (except for trade secrets and confidential commercial information), and to refer the MRTPAs to the Tobacco Products Scientific Advisory Committee. To facilitate the public’s review and comment of Altria’s MRTPA, we will post installments, when submissions become available. The first installment includes the original submission and 3 amendments-i.e., April 10, July 11 and July 18, 2018. FDA will post subsequent amendments in later installments. FDA has announced in the Federal Register when the redacted MRTPA are publicly available on FDA’s website (www.fda.gov/tobacco/).

FDA was granted a waiver under Section 508 of the Rehabilitation Act of 1973. FDA will provide information on how individuals with disabilities may request accommodations to access the content of any publicly available MRTPA on FDA’s website. Individuals requiring such accommodations, or those experiencing problems accessing the MRTPA files, may contact the CTP Call Center by email at AskCTP@fda.hhs.gov or via telephone at 1.877.287.1373 for assistance.

Information about Redactions to the USSTC MRTPA

USSTC’s MRTPA contains non-public information. Section 911(e) of the FD&C Act requires FDA to make a MRTPA publicly available, “except matters in the application which are trade secrets or otherwise confidential, commercial information.”¹ FDA has redacted trade secrets and confidential commercial information from the MRTPA in accordance with federal law.

Questions and Answers

What are examples of trade secrets within USSTC’s MRTPA that FDA redacted?

Examples of trade secrets redacted by FDA include manufacturing processes, ingredient composition, analytical methods, specifications and quality control procedures.

What are examples of confidential commercial information within USSTC’s MRTPA that FDA redacted?

¹ 21 U.S.C. § 387k(e)

Examples of confidential commercial information redacted by FDA include the identity and standard operating procedures of USSTC business consultants, marketing research, and distribution data.

How has FDA designated trade secrets and confidential commercial information within the MRTPA?

The redaction code (b)(4) indicates the areas within the MRTPA where FDA redacted trade secrets and confidential commercial information.

Has FDA redacted any other information within USSTC's MRTPA?

Yes, FDA has also redacted personally identifiable information of clinical study participants, including their initials and dates of birth.

How has FDA designated personally identifiable information within the MRTPA?

The redaction code (b)(6) indicates the areas within the MRTPA where FDA redacted personally identifiable information.

How did FDA determine what confidential commercial information from the application could be released to the public and how much of the application to redact?

FDA cannot release information in an MRTPA that is trade secret or otherwise confidential commercial information without the applicant's consent. FDA, with input solicited from USSTC, determined what information in USSTC's MRTPA should be redacted. Additionally, in some areas, USSTC consented to release certain confidential commercial information that FDA would otherwise have been obligated to redact.

Why are the hyperlinks within USSTC's MRTPA disabled?

FDA applied redactions to the MRTPA with redaction software, which disables hyperlinks during the redaction process. FDA disabled the hyperlinks to prevent unauthorized access to proprietary files, links, metadata and websites.