



Background: 22nd Century Group’s Modified Risk Tobacco Product Applications

On May 17, 2019, 22nd Century Group, Inc. submitted two Modified Risk Tobacco Product Applications (“MRTPAs”) seeking exposure modification orders under Section 911(g)(2) 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 22nd Century Group’s MRTPAs, we will post installments, when submissions become available. The first installment includes the Executive Summary of the Applications. FDA will post the remainder of the Original Applications in later installments. FDA has announced in the Federal Register when the redacted MRTPAs 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 22nd Century Group’s MRTPAs

The MRTPAs contain non-public information. Section 911(e) of the FD&C Act requires FDA to make the MRTPAs 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 MRTPAs in accordance with federal law.

Questions and Answers

What are examples of trade secrets within 22nd Century’s MRTPAs 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 the MRTPAs 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 22nd Century Group's business consultants, marketing research, and distribution data.

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

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

Has FDA redacted any other information within the MRTPAs?

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 MRTPAs?

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

How did FDA determine what confidential commercial information from the applications 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 22nd Century Group, determined what information in the MRTPAs should be redacted. Additionally, in some areas, they consented to release certain confidential commercial information that FDA would otherwise have been obligated to redact.

Why are the hyperlinks within the MRTPAs disabled?

FDA applied redactions to the MRTPAs 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.