First-ever MRTP Application Accepted by US FDA

Before introducing a “new” tobacco product, a manufacturer must obtain the legal authority to do so from the United States Food & Drug Administration (US FDA). While Swedish Match North America was already one of the largest smokeless tobacco brands in the U.S, the company sought an order from the US FDA that would allow a number of its products to be marketed as having a lower risk profile when compared to traditional cigarettes. Such a labeling change constitutes a “new” product per the current regulations and would require filing a Modified Risk Tobacco Product (MRTP) application.

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Swedish Match was required to submit scientific data to the US FDA to support its reduced risk claim. The regulatory approval framework shared some similarities with the pharmaceutical industry. However, unlike the pharmaceutical industry, the regulatory framework for an MRTP was loosely defined and unchartered territory for the sponsor.

Early conversations with GlobalSubmit led Swedish Match to challenge its assumptions about the mechanics of an MRTP filing. Questions as to the scope of the project, Agency expectations for document formatting, and correspondence emerged. Considering all MRTP applications to date had been rejected, Swedish Match recognized the value of a vendor whose track record in electronic regulatory submissions spanned virtually every scenario. “We determined that GlobalSubmit’s FDA experience would best complement our own expertise and give us the greatest probability of success,” said Jim Solyst, VP of Federal Regulatory Affairs.

Swedish Match Challenges

- Legal framework for MRTP application process was only established in 2009. At the time of Swedish Match’s filing, all previous MRTP applications had been rejected by US FDA. Understanding the Agency’s expectations was paramount.
- Determining full scope and formatting requirements associated with filing an MRTP application

Swedish Match Successes

- Successfully submitted Modified Risk Tobacco Product (MRTP) applications seeking risk modification orders Section 911 (g) (1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for 10 smokeless tobacco products.

About Swedish Match

Swedish Match develops, manufactures, and sells products in three main areas—Snus and moist snuff, Other tobacco products (cigars and chewing tobacco), and Lights (matches, lighters, and complimentary products). The stated vision of the company is a world without cigarettes, demonstrating a commitment to improved public health.

Swedish Match corporate headquarters are located in Stockholm, Sweden. The company has nearly 4,400 employees worldwide.

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The standards used to compile the MRTP application were based on GlobalSubmit’s documented best practices and published guidance applicable to electronic submissions. Again, as the MRTP framework was relatively new and malleable, GlobalSubmit adapted procedures and processes to fit the submission type.

Up front, the full scope of the project, as well as folder structures and file naming conventions, were established. The full MRTP application grew to more than 100,000 pages of narrative and supporting studies. All deliverables were laid out, scheduled, and shared with Swedish Match using a custom submission tracker. The tracker provided complete visibility of project status and progress.

In order to meet submission deadlines, clear and frequent communication between project managers was required. Many submission deliverables were received on a rolling basis, and a number of previously received PDF documents of considerable size underwent a series of changes.

“We were very pleased with the quality of GlobalSubmit’s work. Their team validated its stated expertise in submission publishing and was able to nimbly cope with every challenge we faced.”

Swedish Match’s MRTP application for 10 smokeless tobacco products was delivered on schedule to the US FDA Center for Tobacco Products (CTP). It was the first ever MRTP accepted for review by the Agency since the new regulations governing tobacco submissions were established.