The Family Smoking Prevention and Tobacco Control Act

New & Modified Risk Tobacco Products

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as modified by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), gives the Food and Drug Administration (FDA) a powerful tool to improve public health by ensuring that new tobacco products are reviewed prior to being introduced on the market and that tobacco products marketed with claims of reduced harm or risk of tobacco-related disease actually do reduce harm or risk of disease.

Section 910 of the FD&C Act ensures that New Tobacco Products are reviewed and issued a marketing order by FDA prior to being marketed to consumers. Applicants must submit a Premarket Tobacco Application (PMTA) in order to secure such a marketing order from FDA. Section 911 ensures that tobacco products that intend to be marketed with claims of reduced exposure to the harmful substances in tobacco smoke or claims of reduced risk of causing tobacco-related disease actually do reduce exposure or risk of disease. Such new or Modified Risk Tobacco Products (MRTPs) must benefit not only individual smokers, but also the health of the population as a whole.

"The Modified Risk Tobacco Product provisions of the FD&C Act may be valuable tools in the effort to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if companies take advantage of these provisions by making bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both."

— FDA, Modified Risk Tobacco Product Applications: Draft Guidance for Industry, 2012

What is a New Tobacco Product?

A New Tobacco Product is any product that was not commercially marketed in the United States as of February 15, 2007, a date established by the statute. With limited exceptions, New Tobacco Products may not be legally marketed in the U.S. unless FDA has issued an order permitting them to be sold. To issue an order, FDA must evaluate the product based on a public health standard that considers the risks and benefits of the product on the population as a whole, including both users and non-users of tobacco products. When seeking authorization of any New Tobacco Product, manufacturers must submit a Premarket Tobacco Application (PMTA). FDA will evaluate the application to determine whether the product is appropriate for the protection of public health. **FDA will consider the risks and benefits, including the relative health risks of the product, and the likelihood of changes in tobacco initiation and cessation rates.** These considerations will allow for an evaluation of the impact of the New Tobacco Product on morbidity and mortality for the population as a whole. Section 910(c)(1) of the FD&C Act requires FDA to issue an order stating whether the product may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application."

What is a Modified Risk Tobacco Product?

A Modified Risk Tobacco Products (MRTP) is a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Aspects of MRTP marketing may, among other things, communicate the following to consumers:

- The product is less harmful or presents a lower risk of tobacco-related disease than other commercially marketed tobacco products.
- The product reduces exposure to a harmful substance, or does not contain a harmful substance.

Tobacco products cannot be marketed with modified risk claims without a written order from FDA. FDA review of MRTP applications aims to ensure that marketing and claims about the risks of tobacco products are substantiated and supported by scientific evidence, and that the advertising and labeling of these products help the public understand these claims in relation to overall health. FDA must also consider the potential impacts, such as the likelihood that users who would have otherwise quit tobacco use will instead switch to the MRTPs or use MRTPs along with other tobacco products, or the likelihood that non-users of tobacco products will start using an MRTP.

MRTP applications have other unique requirements. For example, FDA is required to make MRTP applications available for public comment before FDA takes action. FDA must also refer MRTP applications to the Tobacco Products Scientific Advisory Committee (TPSAC), which provides advice to FDA. While advice from the TPSAC is not binding, FDA considers it along with other relevant information (including public comments) when making a final decision. The TPSAC consists of representatives from public health and non-voting members of the industry.

FDA can issue an order authorizing the marketing of a product only if the evidence submitted in the application meets the requirements of Section 911 of the FD&C Act. FDA guidance indicates that it intends to issue a decision on an MRTP application within 360 days of its receipt, but this is merely a target, not a statutory requirement.

An FDA order permitting the marketing of an MRTP is not permanent; it is for a fixed period of time. To continue to market a MRTP after the set term, a company must seek renewal of the order and FDA must determine that actual experience in the marketplace confirms the scientific findings contained in the application. In addition, companies will be required to conduct postmarket surveillance and studies and submit the results to FDA annually. FDA will review these results and collect further information about the product's use and health risks. If, at any time, FDA determines that it can no longer make the determinations required for an MRTP order, FDA is required to withdraw the order, thereby extinguishing the authority for the manufacturer to make any reduced exposure or reduced risk claims for the product.

For more information about FDA's regulation of tobacco products, visit FDA's website at **fda.gov/tobacco**.

Philip Morris International (PMI) submitted an application to FDA in December 2016 for authorization to market its novel IQOS tobacco heating system, one of its candidate reduced risk products, in the U.S. as a Modified Risk Tobacco Product.

PMI is committed to transparent sharing of its science. PMI's clinical studies are registered on the U.S. National Institutes of Health website ClinicalTrials.gov. The results of PMI's research are published in peer-reviewed publications: Since 2008, PMI has published over 250 peer-reviewed scientific articles and book chapters describing its approaches, methods, and product assessment studies.

Learn more at PMScienceUSA.com.