Modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a). Any person may submit an application seeking an order under section 911(g) of the FD&C Act.

Section 911(f) of the FD&C Act (21 U.S.C. 387k(f)) requires FDA to refer modified risk tobacco product applications to the Tobacco Products Scientific Advisory Committee (TPSAC) for its recommendations. TPSAC is required to report its recommendations on an application to FDA no later than 60 days after the date the application is referred to them. 21 U.S.C. 387k(f)(2).