FDA Regulation of Tobacco Products: Modified Risk Tobacco Products

The Family Smoking Prevention and Tobacco Control Act (TCA) of 2009 granted the U.S. Food and Drug Administration (FDA) the authority to regulate tobacco products for the first time. The agency now has authority to regulate the manufacture, marketing, sale, and distribution of tobacco products.

The tobacco industry has a long history of misleading the public on the harms of its products. One of the most critical provisions of the TCA requires tobacco companies to receive a marketing order to prove the truthfulness of any claims that their product is "modified risk."

What are Modified Risk Tobacco Products

The term "modified risk tobacco product" is defined in federal law as any product that is sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. A modified risk tobacco product cannot be sold in the US without a marketing order from the FDA. A product manufacturer can apply for a marketing order to make any of the following claims:

- Disease claim: The tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other tobacco products.
- Exposure claim: The tobacco product or its smoke contain a reduced level of a substance or present a reduced exposure to a substance.
- Exposure claim: The tobacco product or its smoke does not contain or is free of a substance.

Cessation claims, including that a product can help a person quit using tobacco, are medical claims that must be approved by FDA as a medical drug or device. Tobacco products cannot make cessation claims.

FDA Regulation of Modified Risk Products

A manufacturer can submit an application to FDA for a marketing order to make a modified risk claim. That application must include at a minimum:

- A description of the proposed product and any proposed advertising;
- The conditions for using the product;
- Sample product labels and labeling;
- All documents (including underlying scientific information) relating to the research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related disease and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health; and
- Data and information on how consumers actually use the tobacco product.

ACS CAN does not believe any product has met the standard to receive a marketing order as a modified risk tobacco product.

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FDA must make the application available to the public for comment. In addition, the application is referred to the Tobacco Products Scientific Advisory Committee for its review and recommendation.

FDA can only issue a modified risk marketing order if the applicant has demonstrated that the tobacco product, as *used by consumers*, will:

- *Significantly* reduce harm and the risk of tobacco-related disease to the individual; and
- Benefit the health of *the population as a whole* taking into account both users of tobacco products and persons who do not currently use tobacco products.

In other words, the manufacturer must prove there will be a reduction in risk or a benefit to health based on how consumers would actually use the product. Simply stating a product is less harmful without providing information on how consumers would use it would be insufficient. When issuing a modified risk marketing order, FDA will review the proposed product, labeling and advertising for use of the claim. Additionally, FDA will determine a fixed time period for permitting the claim at which time the application would have to be renewed. In addition, the manufacturer must conduct post-market surveillance and submit annual reports to FDA. FDA has the authority to remove a modified risk product from the market if it is not having the intended public health effect.

So-called "Light," "Low," and "Mild" Cigarettes

As health concerns about smoking started to emerge in the 1950s and 1960s, cigarette manufacturers created so-called "light" cigarettes, marketing them as healthier with less tar and less nicotine. Due to the design of these cigarettes, smokers actually smoked longer, inhaling more deeply and more frequently to get their desired dose of nicotine. These design changes may have led to an increase in lung cancer cases. Cigarette manufacturers knew these products posed no less risk, yet fraudulently sold them to Americans as such. Decades later, the TCA outright prohibited the terms "light," "low," and "mild."

FDA Decisions

As of September 2022, the FDA has permitted modified risk claims for four products: (1) Swedish Match USA, Inc. snus, (2) Philip Morris Products S.A. IQOS, (3) 22nd Century Group, Inc. VLN low nicotine cigarettes, and (4) Philip Morris Products S.A. IQOS 3 System holder and Charger.

1. Swedish Match USA, Inc. is permitted to make a disease risk claim for eight of its snus products, including several mint-flavored products.
2. Philip Morris Products S.A. is permitted to make an exposure risk claim for its IQOS products, including menthol-flavored heatsticks. Philip Morris Products S.A. was denied a disease risk claim.
3. 22nd Century Group, Inc. is authorized both modified risk and exposure modification orders for their lower nicotine combusted cigarettes, including lower nicotine menthol-flavored cigarettes, allowing the products to be marketed with reduced exposure claims that they include "95% less nicotine."
4. Philip Morris Product S.A. can market the IQOS 3 System Holder and Charger noting that the product "heats tobacco but does not burn it." In addition, applications are under review for six R.J. Reynolds Camel Snus products and U.S. Smokeless Tobacco Company's Copenhagen Snuff Fine Cut.

On August 23, 2022, the FDA issued a Final Guidance on Tobacco Product Perception and Intention Studies for tobacco product manufacturer applicants to develop and conduct studies that assess, among other things, individuals' perceptions of tobacco products, understanding of tobacco product information and intentions to use tobacco products.

ACS CAN's Position

ACS CAN, with its tobacco control partners, has opposed the tobacco industry's existing and proposed modified risk marketing orders. All tobacco products are unsafe, including those the FDA decides are permitted to use a modified risk claim. Tobacco products contain nicotine, which is highly addictive. The U.S. Surgeon General reports that smoking cessation is beneficial at any age and "only complete cessation of all tobacco products fully eliminates all tobacco-related health risks."[i]

The modified risk tobacco product applications to date have been insufficient in proving that the products as used by consumers would lead to a reduction in risk. In addition, all the applications have lacked any information on the impact on youth – which is required under the law. In addition, local and state governments should not exempt products that have received a marketing order for a modified risk claim from their tobacco control laws, nor tax them at lower rates than cigarettes and other tobacco products. ACS CAN will continue to urge the FDA to deny any applications that are incomplete and do not meet the standard required by the Tobacco Control Act.

References

[i] Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.