FDA's CTP Regulation of Tobacco Products: Modified Risk Claims

The Family Smoking Prevention and Tobacco Control Act (TCA) prohibits tobacco manufacturers from using misleading descriptors about their products and requires a substantive scientific review by the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) prior to using any "modified risk" claim. This is one of the most important provisions of the TCA as it directly addresses the tobacco industry's deceptive marketing practices about the harm of its products.

What are Modified Risk Claims?

The TCA defines a modified risk tobacco product (MRTP) 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. There are three types of modified risk claims a manufacturer can apply for:

- 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 contains a reduced level of a substance or presents a reduced exposure of a substance.
- Exposure claim: The tobacco product or its smoke doesn't contain, or is free of, a substance.

Cessation claims, including that a product can help a person quit using tobacco, are medical claims that are regulated by FDA's Center for Drug Evaluation and Research (CDER). To make such claims, products must demonstrate safety and effectiveness and provide evidence supporting the proposed labeling and intended use, including any health claims, of the product. ***Tobacco products regulated by CTP cannot make cessation claims.***

	FDA-Approved Cessation Medication	**FDA-Authorized MRTP**
FDA Center responsible for regulation	Center for Drug Evaluation and Research (CDER)	Center for Tobacco Products (CTP)
Products Regulated	Cessation Medications	Tobacco Products
Purpose	Help people quit using tobacco products.	Provide information that a tobacco product may pose less risk or contain less of a substance than another tobacco product.
Standard under the law	Safe and effective for helping people quit when used as directed.	The claim is factual and will have a net public health benefit to the population as a whole based on how consumers will actually use the product.
Can it claim to help people quit?	Yes.	No.
Is it a tobacco product?	No.	Yes.

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CTP Process for Modified Risk Claims

Process: The TCA requires a manufacturer to submit an application to CTP for the sale of an MRTP. Applications are product specific. CTP must make the application available to the public for comment, and it is referred to the Tobacco Products Scientific Advisory Committee for its review and recommendation.

Applications must include at a minimum:

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

CTP action on the application includes issuance of a modified risk marketing order or denial or an application deficiency letter in which the applicant is required to respond before further CTP action. When issuing a modified risk marketing order, CTP must establish a fixed time period for permitting the claim after which time it would need to be renewed. The manufacturer must conduct post-market surveillance and submit annual reports to CTP. CTP has the authority to revoke a modified risk marketing order if it is not having the intended public health impact.

Public Health Standard: To issue a modified risk granted order, CTP must determine if the applicant has demonstrated that the tobacco product *as used by consumers* will:

- Significantly reduce the harm and the risk of tobacco-related disease to individual tobacco users; and
- Benefit the health of the population as a whole, taking into account both users of tobacco products and people who do not currently use tobacco products. To make this determination, CTP must take into account:
    - The relative health risks to individuals who use the product that is the subject of the application;
    - The increased or decreased likelihood that people who currently use tobacco products would switch to the product that is the subject of the application;
    - The increased or decreased likelihood that people who do not use tobacco products would start using the product that is subject of the application; and
    - The risks and benefits of using the product that is the subject of the application compared to FDA-approved cessation products.

In other words, the manufacturer must prove that (a) the claim is scientifically true and (b) that there will be a net public health benefit to the population as a whole based on how consumers would actually use the product. It is insufficient to simply state a product poses less exposure or disease risk without providing information on how consumers would use the product.

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CTP Modified Risk Marketing Orders

CTP provides a list of modified risk marketing orders that were granted on its website, along with its decision summary.

Tobacco Industry Violations

The tobacco industry continues to market and sell tobacco products with modified risk claims and medical claims without FDA authorization or approval. For example, according to a 2026 U.S. Government Accountability Office report, thousands of unauthorized e-cigarette products were being sold, and yet the Department of Justice has taken only 88 civil or criminal enforcement actions against illegal e-cigarette products since 2023.

Decisions on product applications hold no value in protecting the public health without comprehensive, effective federal enforcement. FDA has taken minimal enforcement actions against manufacturers making numerous illegal modified risk and medical claims about their products. ACS CAN, along with its tobacco control partners, has also sent letters to FDA alerting them to unauthorized tobacco industry marketing of products.

Peddling Harm

The tobacco industry is flooding the market with products such as e-cigarettes and nicotine pouches, the vast majority of which are illegal and fraudulently market them as less harmful.

This is not new. In response to health concerns of smoking emerging in the 1950s and 1960s, cigarette manufacturers created so-called "light" cigarettes, marketing them as healthier with less tar and nicotine. In fact, design changes in these cigarettes may have led to an increase in lung cancers.

ACS CAN's Position

ACS CAN, along with its tobacco control partners, has opposed all MRTP applications to date. The applications thus far have been insufficient in proving that the products, as actually used by consumers in the real world, would lead to a reduction in disease or exposure risk. In addition, all the applications have lacked information on the impact on youth – which is required under the law. ACS CAN will continue to monitor this process, provide public comments on the applications, and urge CTP to deny any application that does not meet the standard under the law.

Products that have been granted modified risk orders from CTP should not be exempt from fact-based federal, state, or local tobacco control policies, nor should they be taxed at lower rates than other products.

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