FDA's CTP Regulation of Tobacco Products: Premarket Review

The Family Smoking Prevention and Tobacco Control Act (TCA) requires manufacturers of all new tobacco products to submit an application to the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) for premarket review to prove that the sale of their product is "appropriate for the protection of public health" (APPH) prior to going on to the market. This is one of the most important provisions of the TCA, and was intended to prevent new, harmful tobacco products from ever being sold. Unfortunately, the premarket review of all new tobacco products has never taken full effect due to lack of enforcement by the agency, the tobacco industry continuing to sell new products without CTP authorization and implementation disruptions.

What is Premarket Review?

Under the TCA, a tobacco manufacturer is required to submit a premarket tobacco application (PMTA) to CTP for scientific review of the new product prior to offering it for sale. Based on review of the PMTA, the agency then issues a marketing denial order (MDO) or a marketing granted order (MGO). A new tobacco product is defined as any product (including those products in test markets):

- That was not commercially marketed in the U.S. as of February 15, 2007; or
- Any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Public Health Standard: Because the FDA Center for Drug Evaluation and Research's (CDER) traditional standard of "safe and effective" for other products like drugs and food cannot apply to tobacco products, regulated separately by CTP, the TCA established a new standard of "appropriate for the protection of public health" (APPH or "the public health standard"). CTP must use this standard to determine whether to authorize sales of the product. CTP must consider:

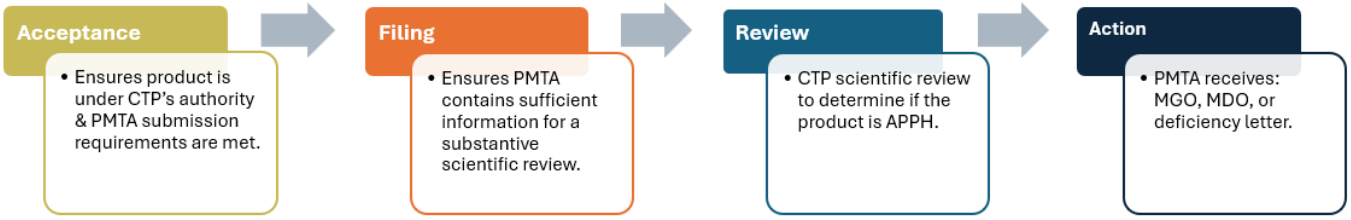
- Risks and benefits to the population as a whole, including people who would use the new tobacco product as well as nonusers;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the new tobacco product were available; and
- Whether people who currently do not use any tobacco product would be more or less likely to begin using tobacco products if the new tobacco product were available.

Process: Tobacco product manufacturers' applications must include information on known or potential health risks, ingredients, additives, and other components, manufacturing and processing, samples, and any other information CTP requests. The CTP process includes application acceptance, filing, and substantive scientific review for CTP to take action. CTP has the option of submitting the application to the Tobacco Products Scientific Advisory Committee for review. CTP action is issuance

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of an MDO or MGO, or an application deficiency letter in which the applicant is required to respond before further CTP action.

Importantly, **FDA does not approve tobacco product applications or tobacco products to be sold in the U.S.**; rather, it "authorizes" sale of the product(s). The TCA prohibits manufacturers from explicitly or implicitly saying that their product has been "approved" by the FDA.



PMTA Marketing Orders

CTP maintains a searchable tobacco products database for products that received MGOs and are therefore legally allowed to be sold in the U.S. CTP also created webpages specific to e-cigarettes and nicotine pouches that are legally allowed to be sold in the U.S.

Tobacco Industry Violations

In direct violation of the TCA, the tobacco industry continues to market and sell tobacco products without FDA authorization. For example, according to a 2026 U.S. Government Accountability Office report, thousands of unauthorized e-cigarette products were being sold, and the Department of Justice (DOJ) has taken only 88 civil or criminal enforcement actions against illegal e-cigarette products since 2023.

ACS CAN, along with its tobacco control partners, has also sent letters to FDA alerting them to unauthorized tobacco industry marketing or sales of products.

FDA Enforcement of the TCA

Decisions on product applications hold no value in protecting the public health without comprehensive, effective FDA enforcement. FDA has also failed to take enforcement actions against numerous products that remain on the market illegally to this day. In May 2024, ACS CAN joined a letter that included 78 public health organizations urging FDA, DOJ, and U.S. Customs and Border Protection (CBP) to utilize all the enforcement tools at their disposal to clear the market of illegal e-cigarette products. The following concrete steps, many of which were included in the letter, should be applied to FDA's enforcement of all illegal tobacco products.:

- FDA should make more frequent use of the full range of available enforcement tools, especially stronger tools such as civil monetary penalties, no-tobacco-sale orders, product seizures, import restrictions, injunctive actions, and criminal prosecutions.

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- FDA must seek greater civil monetary penalties to create real incentives to comply with the law.
- DOJ must prioritize tobacco product enforcement, and the process for bringing actions for injunctive relief must be streamlined. Because the FDA does not have its own litigation capability, it must involve the DOJ in seeking injunctive relief from courts against the marketing of unauthorized products.
- CBP and FDA must prioritize efforts to stop illegal importation of illegal and unauthorized products.
- Enforcement actions must be brought against all parties in the supply chain, including manufacturers, distributors, importers, and retailers.
- FDA must end its broad exercise of enforcement discretion and fully enforce the law against all unauthorized products, including those with pending marketing applications before the FDA.

Major Disruptions in Premarket Review

In addition to the tobacco industry bypassing the PMTA process by continuing to illegally sell products in the U.S., there have been three major disruptions to CTP's premarket review process: (1) delays in finalizing the Deeming Rule, (2) delays in enforcing the premarket review process, and (3) CTP's decision to permit certain e-cigarettes and nicotine pouch products that filed their PMTA but not received MGOs to remain on the market.

Deeming Rule Delays: In 2009, the TCA explicitly granted FDA authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and created CTP. It also provided the agency authority to regulate all other tobacco products, but CTP did not finalize the rule – known as "the Deeming Rule" – regulating e-cigarettes and other new products until 2016. This years-long delay allowed the tobacco industry to flood the U.S. market with new tobacco products that went completely unregulated until 2016. Even then, delays continued.

Premarket Review Enforcement Delays: Once the Deeming Rule was finalized in 2016, CTP recognized that it could not enforce pulling all newly illegal tobacco products off the market when the rule took effect. Instead, as part of the rule, CTP created a compliance period of up to three years for products to continue to be sold in the U.S. if a manufacturer submitted its PMTA. Then in 2017, CTP announced it would permit those products that had submitted a PMTA but not yet undergone a completed scientific review to stay on the market virtually indefinitely without authorization, meaning thousands of illegal products remained on the market.

Illegal E-cigarette and Nicotine Pouch Products without MGOs to Stay on the Market: Similarly, in May 2026, CTP announced it would permit e-cigarette and nicotine pouch products that have filed their PMTAs to stay on the market until the agency has made a marketing determination. As a result, thousands of illegal products could remain on the market in the U.S., potentially for years, without a completed scientific review.

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Litigation

Public Health Partners' Litigation Against FDA PMTA Enforcement Delays

ACS CAN and its public health partners sued the FDA in 2018 over its decision to permit newly illegal products to stay on the market virtually indefinitely. In deciding for the public health groups in 2019, U.S. District Judge Paul W. Grimm found that the FDA had exceeded its legal authority by not carrying out its statutory mandate to review these products, and the FDA's delay had played a role in the skyrocketing use of e-cigarettes by youth. Judge Grimm ruled that FDA's delay gave "manufacturers responsible for the public harm a holiday from meeting the obligations under the law."

Due to this court decision, manufacturers were forced to submit PMTAs for new products to the agency in 2020. However, CTP took far longer than expected to complete its review of the applications, resulting in a requirement that the agency submit regular status reports to the judge regarding its review of millions of backlogged applications.

The 2026 CTP announcement once again required a response from ACS CAN and its public health partners. In July 2026, ACS CAN and its partners filed a federal lawsuit challenging FDA's new enforcement policy that allows e-cigarette and nicotine pouch products to be marketed and sold without the scientific review and marketing authorization required by federal law. This new lawsuit is very similar to the original one filed by partners in 2018 because the legal issues are largely the same.

Public Health Partners' Litigation in Support of CTP MDOs

As CTP began issuing marketing MDOs to manufacturers for certain flavored e-cigarette products in accordance with the TCA, e-cigarette manufacturers sued to keep their products on the market. Beginning in October 2021, ACS CAN joined other tobacco control groups in participating as amicus curiae (or "friend of the court") in numerous cases across the nation. The briefs supported the MDOs issued by CTP for dozens of flavored tobacco products, culminating in an amicus filing at the U.S. Supreme Court (SCOTUS) in September 2024 in a critical case determining whether many of these products can continue to be sold and lure children into a lifetime of nicotine addiction.

Public health partners' briefs consistently provided the courts with scientific data on the epidemic of e-cigarette use by children, background on how the tobacco industry has long understood that almost all new tobacco users begin their addiction as children, and that flavored products are essential to successfully market the products to young people.

In a unanimous victory for public health, SCOTUS ruled 9–0 in favor of FDA in its decision to issue MDOs for these products in April 2025.

ACS CAN's Position

ACS CAN continues to advocate for CTP enforcement of premarket review of all new tobacco products as one of the key components of the TCA to prevent the marketing of products unless the

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manufacturer has received FDA's CTP authorization based on submitted scientific information that the product meets the APPH standard. This includes advocating for the denial of all PMTAs for flavored tobacco products as there is no net public health benefit of these products. ACS CAN will continue to use regulatory, legislative, and judicial levers to ensure FDA's CTP is using the full weight of its authority and that of its partner federal agencies to protect public health.

ACS CAN advocates for the inclusion of all tobacco products in fact-based federal, state, or local tobacco control policies. No tobacco product, including those seeking or with MGOs should be exempt from these policies, nor taxed at a lower rate than cigarettes.

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