Flowchart: Compliance and Enforcement Processes for Unauthorized Electronic Nicotine Delivery Systems (ENDS) Products (Page 1 of 2)

New ENDS products must be authorized by FDA before marketing and sale in the United States

Every manufacturer and importer with a new tobacco product not commercially marketed in the U.S. as of Feb. 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after Feb. 15, 2007, must submit an application and generally obtain FDA authorization before marketing a new tobacco product.

- Manufacturers and importers of ENDS products generally must submit a premarket tobacco application (PMTA).
- CTP/Office of Science reviews the PMTA to determine if marketing is Appropriate for the Protection of the Public Health.

Resources for Industry

- Tobacco guidance documents
- Tobacco compliance webinars
- Small Business Assistance for Tobacco Product Industry
- FDA's Searchable Tobacco Products Database
- Market and Distribute a Tobacco Product

FDA monitors industry compliance with the premarket authorization requirements by:

Online Surveillance

CTP monitors the online activities of ENDS manufacturers, distributors, importers, and retailers to help assess compliance with the premarket authorization requirements of the Food, Drug, and Cosmetic Act (FD&C Act). For example, FDA monitors tobacco websites, online media advertisements, and other promotional activities and evaluates complaints submitted to the Potential Tobacco Violation Reporting system and FDA's Safety Reporting Portal.

Inspections/ Investigations

FDA has authority to inspect and investigate domestic establishments, including vape shops, that manufacture, process, sell or distribute tobacco products to determine compliance with applicable provisions of the law, including premarket authorization requirements.

Webinar: Small Tobacco Product Manufacturers, Domestic Establishment Inspections

Import Screening/ Import Alerts

FDA screens certain tobacco product imports for compliance with applicable laws, including the premarket authorization requirements, before those imported products, including ENDS, enter the United States FDA also regularly addresses the importation of illegal e-cigarettes by placing certain firms and products on an FDA import alert red list. Import Alerts inform the FDA field staff and the public that the agency has enough evidence to allow for detention without physical examination (DWPE) of products that appear to be in violation of the laws FDA implements.

Webinar: Updates for Importers

Review Regulatory Submission Information

CTP monitors the activities of tobacco product manufacturers by reviewing required submissions, such as domestic establishment registrations, and product listings. This helps FDA to identify potential violations.

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Based on all relevant information, including surveillance, inspection, and/or regulatory submission review, FDA determines compliance with applicable provisions of the law, including premarket authorization requirements

Compliance with the law?

NO

Warning Letter (WL) —Initial warning to manufacturers, distributors, and/or retailers

Generally, when companies are manufacturing, marketing, and/or selling unauthorized tobacco products in the United States, FDA will typically first issue a warning letter in an attempt to achieve voluntary compliance with the law. There is no requirement, however, for FDA to send a warning letter before the agency can initiate an enforcement action.

- Webinar: What a Manufacturer or Vape Shop Should Do After Receiving a Warning Letter
- Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products

YES

As long as there are no other violations, products that have premarket authorization and pre-existing tobacco products may be manufactured, imported, distributed, and sold to consumers in the United States.

Firm has opportunity to respond to the WL with plan to come into compliance

FDA monitors industry compliance with the premarket authorization requirements

Compliance with the law?

YES

NO

Civil Money Penalty (CMP) *

A CMP is an administrative enforcement action that seeks to impose a fine for certain violations of the law relating to tobacco products. This includes violations related to manufacturing, distributing, and/or selling unauthorized new tobacco products.

Injunction*

An injunction is a civil judicial process initiated to stop current violations of the law and prevent them going forward, halt the flow of violative products in interstate commerce, and correct the conditions that caused the violation to occur. The U.S. Department of Justice (DOJ) institutes judicial enforcement actions, such as injunctions, under the FD&C Act on behalf of FDA in federal court. In injunction cases, defendants may have the opportunity to settle the matter, for example by signing consent decrees of permanent injunction. A consent decree is a written agreement, signed by the judge and entered as a court order, in which parties agree to certain terms and conditions to settle the lawsuit, such as further inspections and the destruction of the unauthorized tobacco products in defendants' possession, custody, or control.

Seizure*

A seizure is a judicial action brought against an unlawful FDA-regulated product, including because it is adulterated and/or misbranded within the meaning of the FD&C Act. DOJ institutes judicial seizure actions under the FD&C Act on behalf of FDA in federal court by filing a Complaint for Forfeiture and obtaining a warrant for arrest, directing the United States Marshals Service to seize (take possession or place in constructive custody of the court) the unlawful product. The purpose of such an action is to remove specific violative goods from commerce.

Criminal Prosecution*

FDA's Office of Criminal Investigations conducts criminal investigations of unlawful activities involving FDA-regulated products and works with DOJ to prosecute those responsible for the illegal conduct.

*This is a high-level summary of FDA's tobacco compliance and enforcement activities that is not intended to be all inclusive. FDA also has additional compliance and enforcement tools to address the manufacture, importation, distribution, and/or sale of unauthorized ENDS products, including import refusals.