RECENT CHANGES THAT IMPACT THE SALE OF TOBACCO PRODUCTS IN RETAIL ESTABLISHMENTS

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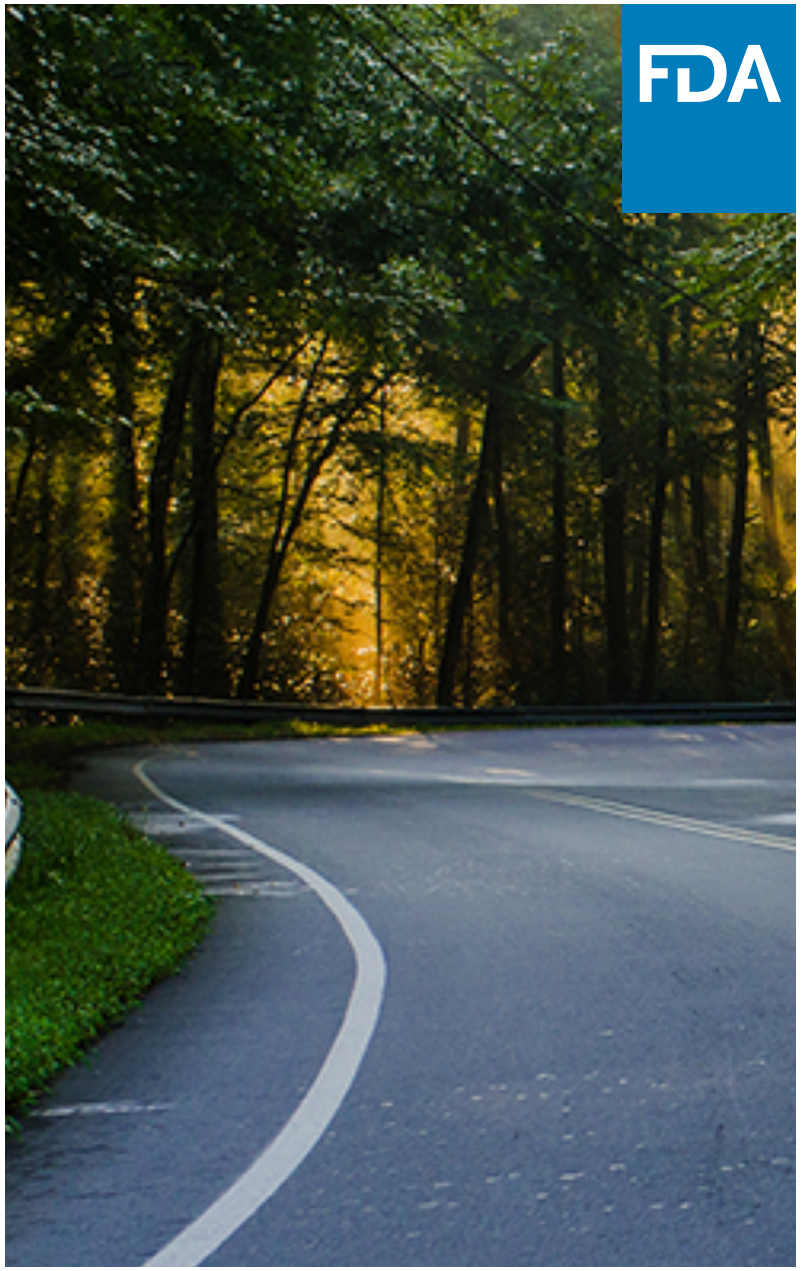
CENTER FOR TOBACCO PRODUCTS

TOPICS

- Overview of Changes Made to the Federal Food, Drug, and Cosmetic Act (FD&C Act) to Increase the Federal Minimum Age of Sale of Tobacco Products to 21
- Overview of Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products On The Market Without Premarket Authorization Guidance (Enforcement Priorities Guidance)
- Enforcement
- Additional Resources



FEDERAL MINIMUM AGE OF SALE OF TOBACCO PRODUCTS

- On **Dec. 20, 2019**, the FD&C Act was amended to raise the minimum age of sale of tobacco products from 18 to 21 years.
- It is now illegal to sell tobacco products, including cigarettes, cigars, and e-cigarettes, to anyone under the age of 21. There are **no exemptions** from this requirement.
- Retailers can ensure they follow the law by taking measures to ensure individuals purchasing tobacco products are 21 or older, including manually checking IDs.
- Current regulations require retailers to verify a tobacco purchaser's age by means of photo identification that contains the bearer's date of birth if the purchaser is under the age of 27.

FEDERAL MINIMUM AGE OF SALE OF TOBACCO PRODUCTS – WHAT RETAILERS SHOULD KNOW

- The law amending the federal minimum age of sale of tobacco products to 21 also directs FDA to update its current regulations on the sale and distribution of tobacco products.

- FDA fully intends to make appropriate changes to its regulations, and will provide additional details as they become available.

- **Retailers must:**
  - Only sell tobacco products to individuals 21 years of age or older.
  - Continue to comply with the requirements under FDA's regulations, and **must not,** for example:
    - Sell tobacco products using vending machines unless the retailer ensures that no person younger than the age of 18 is present, or permitted to enter, at any time;
    - Distribute free samples of tobacco products with limited exceptions for smokeless tobacco products; and
    - Sell single cigarettes.

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW

- On **Jan. 2, 2020,** FDA published a guidance for industry titled, “Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization.” (Enforcement Priorities Guidance).

- This guidance document describes how FDA intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.
  - Under the FD&C Act, “new” tobacco products—meaning those tobacco products that were not on the market as of Feb. 15, 2007—must obtain premarket authorization from the FDA before they may be legally marketed.
  - ENDS products became subject to these premarket requirements in August 2016.
  - FDA previously provided extended compliance dates for these premarket requirements for most ENDS products. FDA has changed this enforcement policy.

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW: WHAT ARE THE NEW ENFORCEMENT PRIORITIES?

- On **Feb. 6, 2020,** 30 days after issuance of the final Enforcement Priorities Guidance, FDA began prioritizing enforcement of the premarket review requirements for certain ENDS products:

  1) Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
  2) All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
  3) Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

- FDA intends to prioritize enforcement for any ENDS product that is offered for sale after May 12, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW: WHAT ARE CARTRIDGE-BASED ENDS?

- Cartridge-based ENDS are ENDS products that consist of, include, or involve a cartridge or pod that holds liquid that is to be aerosolized through product use.
- Some examples of ENDS products include vapes or vape pens, personal vaporizers, and e-cigarettes.
- A cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an ENDS.

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW: WHAT FLAVORS ARE COVERED?

- Flavored, cartridge-based ENDS products subject to enforcement prioritization include flavored, cartridge-based ENDS products that are not tobacco- or menthol- flavored.

- Examples of flavored, cartridge-based ENDS products that are subject to enforcement prioritization include, but are not limited to:
  - Cartridge-based ENDS products containing flavors, such as:
    - Bubble Gum, Mango, Strawberry, Mint
  - Cartridge-based ENDS products containing a flavor in addition to menthol or tobacco, such as:
    - Mango Menthol
    - Iced Strawberry Menthol

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW: WHAT RETAILERS SHOULD DO

- In light of the enforcement priorities announced in the guidance, retailers should not sell any flavored, cartridge-based ENDS products (other than a tobacco- or menthol-flavored ENDS product) to anyone, regardless of their age.

- Beginning **Feb. 6, 2020,** FDA intends to prioritize enforcement of the premarket review requirements for such products, among others, including against retailers selling such products.

- Flavored, cartridge-based ENDS products (other than tobacco-or menthol-flavored ENDS products) should not be offered for sale, displayed for sale, or available in any area the public may access.

- FDA encourages retailers to contact their suppliers or the product manufacturers to discuss possible options for the affected flavored, cartridge-based ENDS products that they may have in their inventory.

ENFORCEMENT PRIORITIES GUIDANCE OVERVIEW: WHAT RETAILERS SHOULD KNOW

- If a flavored, cartridge-based ENDS product receives premarket authorization from the FDA, retailers may sell that product.

- When an ENDS product receives premarket authorization, FDA will list the product on the premarket tobacco product marketing orders page: https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders.

- It is illegal to sell any tobacco products to individuals under the age of 21, including all ENDS—regardless of whether or not the product is subject to the enforcement priorities outlined in the Enforcement Priorities Guidance or has premarket authorization.

RETAILER REQUIREMENTS SUMMARY

- **Retailers may not sell tobacco products to anyone under the age of 21 – There are no exemptions.**
  - Retailers can manually check IDs to make sure they do not sell to anyone under the age of 21.

- **Retailers must comply with existing tobacco product regulations.**
  - Examples: Do not sell tobacco products using vending machines unless the retailer ensures that no person younger than the age of 18 is present, or permitted to enter, at any time; do not distribute free samples of tobacco products with limited exceptions for smokeless tobacco products; and do not sell single cigarettes.

- **Retailers should not sell flavored, cartridge-based ENDS to anyone – regardless of age.**
  - Beginning **Feb. 6, 2020,** FDA intends to prioritize enforcement of the premarket review requirements for such products, among others, including against retailers selling such products.
  - Flavored, cartridge-based ENDS products (other than tobacco- or menthol-flavored ENDS products) should not be offered for sale, displayed for sale or available in any area the public may access.

ENFORCEMENT

- Generally, the first time FDA finds violations of the law during a tobacco retailer inspection, FDA issues a Warning Letter.

- A Warning Letter is the agency's advisory action used to try to achieve prompt voluntary compliance with the law and establish prior notice.

ENFORCEMENT

- Retailers should respond to a Warning Letter within 15 working days, in writing, by mail or email.
  - A Warning Letter response should include:
    - Steps the retailer will take to correct the violation(s) and prevent future violations (for example, stop selling the items, etc.); and
    - The retailer's current contact information including telephone number and email address.
- Retailers should promptly correct the violations listed and comply with all applicable laws and regulations.
- Failure to comply may result in FDA initiating further actions including, but not limited to, civil money penalties, criminal prosecution, and/or injunction.

ADDITIONAL RESOURCES

- Additional information for retailers, including retailer requirements, can be found at https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailer-training-and-enforcement.
- Enforcement Priorities Guidance Available here: https://www.fda.gov/media/133880/download.
- Sign-up for email updates from CTP at https://www.fda.gov/tobacco-products/ctp-newsroom.
- Please direct any additional questions to: AskCTP@fda.hhs.gov or at 1-877-287-1373.
- CTP's Office of Small Business Assistance (OSBA) can be reached at SmallBiz.Tobacco@fda.hhs.gov or at 1-877-287-1373.