CENTER FOR TOBACCO PRODUCTS

FDA Requirements

for NEWLY REGULATED TOBACCO PRODUCTS

On May 10, 2016, the U.S. Food and Drug Administration issued a new regulation for additional tobacco products (including their components and parts, but excluding accessories) intended for human use that FDA did not regulate previously.

Examples of these newly regulated tobacco products include:

- Electronic nicotine delivery systems (e.g., e-cigarettes, vaporizers, vape pens)
- Pipe tobacco
- Cigars
- Hookah tobacco
- E-liquid containing nicotine
- Cigar tips
- Filters
- Any other products that are made or derived from tobacco

RETAILER INFORMATION

You are considered a tobacco *retailer* if you:

- Sell any newly regulated tobacco product to individuals for personal use; OR
- Sell electronic nicotine delivery system (ENDS) replacement pieces or ENDS hardware to individuals for personal use.

RETAILERS must comply with the following requirements:

- Sell newly regulated tobacco products made or derived from tobacco only to individuals age 18 and older. (Retailers must comply with more restrictive state or local laws, where applicable).
  (Compliance Date: August 8, 2016)
- Check the photo ID of everyone under the age of 27 who attempts to purchase newly regulated tobacco products made or derived from tobacco.
  (Compliance Date: August 8, 2016)
- Sell newly regulated tobacco products made or derived from tobacco in vending machines only if located in facilities where no person younger than age 18 is present or permitted to enter at any time. Vending machine sales of these products are otherwise prohibited.
  (Compliance Date: August 8, 2016)
- Do not give away free samples of newly regulated tobacco products.
  (Compliance Date: August 8, 2016)
- Stop selling newly regulated tobacco products whose label, labeling, or advertising uses claims of modified risk—"lower risk," "less harmful," or "contain a reduced level of a substance" than another commercially marketed tobacco product—without an FDA order in effect.
  (Compliance Date: August 8, 2016)
- If you direct or create your own ads and/or packaging for cigars, submit a cigar warning plan to FDA.
  (Compliance Date: August 10, 2017)
- Stop selling newly regulated tobacco products whose label, labeling, or advertising uses claims of modified risk—"low," "light," or "mild"—without an FDA order in effect.
  (Compliance Date: December 8, 2017)
- Display a warning sign for cigars sold individually without product packaging.
  (Compliance Date: August 10, 2018)
- If you create or direct product packaging or advertising for cigarette tobacco, roll-your-own tobacco, or newly regulated "covered" tobacco products made or derived from tobacco, you must display a nicotine warning statement on these items.
  (Compliance Date: August 10, 2018)
- **Note:** FDA encourages retailers to contact their supplier or distributor to determine which tobacco products in their inventory have appropriate marketing authorizations or are grandfathered.

Depending on your establishment's activities, you may be a tobacco retailer, a tobacco manufacturer, or both. The information on this page and the next page is an overview and NOT an exhaustive list of the requirements for tobacco product retailers and manufacturers.[1]

[1] FDA has regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco since 2009, and requirements for those products are currently in effect. For more information about FDA's regulation of tobacco retailers and manufacturers, please visit FDA's website at www.fda.gov/tobacco.

MANUFACTURER INFORMATION

You are considered a tobacco *manufacturer* if you:

- Manufacture, fabricate, assemble, process, or label a tobacco product; OR
- Mix or prepare e-liquids; OR
- Create or modify aerosolizing apparatuses; OR
- Repackage or relabel electronic nicotine delivery system (ENDS) products.

MANUFACTURERS must comply with the following requirements:

- Do not give away free samples of newly regulated tobacco products.
  (Compliance Date: August 8, 2016)
- Stop marketing or distributing newly regulated tobacco products whose label, labeling, or advertising uses the claims of modified risk—"lower risk," "less harmful," or "contain a reduced level of a substance" than another commercially marketed tobacco product—without an FDA order in effect.
  (Compliance Date: August 8, 2016)
- Register your establishment upon first engaging in the manufacturing of a tobacco product that is sealed in final packaging and intended for consumer use and register annually on or before December 31st of each year. Submit to FDA your product listing information at the time of first registration and submit certain changes biannually, once during June and once during December.
- Submit ingredient listings to FDA for newly regulated tobacco products that are sealed in final packaging and intended for consumer use.
  (Compliance Dates: May 8, 2018; Small-scale manufacturer—November 8, 2018)
- Submit tobacco health documents for tobacco products that are sealed in final packaging and intended for consumer use to FDA.
  (Compliance Dates: February 8, 2017; Small-scale manufacturer—November 8, 2017)
- If you create or direct ads or packaging for cigars, submit a cigar warning plan to FDA.
  (Compliance Date: August 10, 2017)
- Do not sell newly regulated tobacco products that are sealed in final packaging and intended for consumer use without a marketing order in effect, unless they are grandfathered tobacco products.
  (Submit a Premarket Tobacco Product Application, Substantial Equivalence Report, or a Substantial Equivalence Exemption request by August 8, 2021, for combustible tobacco products or August 8, 2022, for noncombustible tobacco products.)
- Stop manufacturing and distributing newly regulated tobacco products whose label, labeling, or advertising uses the claims of modified risk—"low," "light," or "mild"—without an FDA order in effect.
  (Compliance Dates: Stop manufacturing—November 8, 2017; Stop distributing—December 8, 2017)
- Stop manufacturing, distributing, or advertising cigars without the required warnings.
  (Compliance Dates: Stop manufacturing—August 10, 2018; Stop advertising—August 10, 2018; Stop distributing—September 11, 2018)
- If you create or direct product packaging or advertising for cigarette tobacco, roll-your-own tobacco, or newly regulated tobacco products made or derived from tobacco, you must display a nicotine warning statement on these packages or ads.
  (Compliance Dates: Stop manufacturing—August 10, 2018; Stop advertising—August 10, 2018; Stop distributing—September 11, 2018)
- Packaging for newly regulated tobacco products must bear required statements, including, but not limited to, the name and place of business, the quantity of the contents, and "Sale only allowed in the United States."
  (Compliance Date: Stop distributing without required statements—August 10, 2018)
- Submit information to FDA on harmful and potentially harmful constituents for newly regulated tobacco products sealed in final packaging and intended for consumer use.
  (Compliance Date: November 8, 2019)

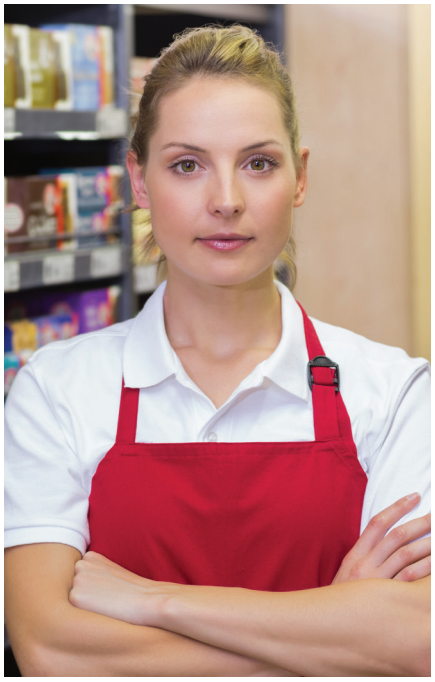
THIS IS OUR WATCH℠
WE I.D. TOBACCO PURCHASES

FDA has developed a new education program called "This Is Our Watch." This program helps tobacco retailers better understand FDA tobacco regulations, the importance of compliance, and the greater purpose—protecting the nation's youth from the harms of tobacco use. FDA offers a full toolkit of free resources—including posters, stickers, age verification tools, and more—to help retailers better comply with federal tobacco regulations.

DID YOU KNOW retailers can use the camera feature on their smartphone to scan a driver's license to determine if a customer is at least 18 years of age? Check out the new **FDA Age Calculator** app for tobacco retailers.

Look for:

FDA
AGE CALCULATOR



NEED MORE INFORMATION?

For more information about FDA's regulation of tobacco retailers and manufacturers, and to order **"This Is Our Watch"** resources, please visit FDA's website at **www.fda.gov/tobacco.**

QUESTIONS?

If you have any questions, please contact the Center for Tobacco Products at AskCTP@fda.hhs.gov or at 1.877.CTP.1373.

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