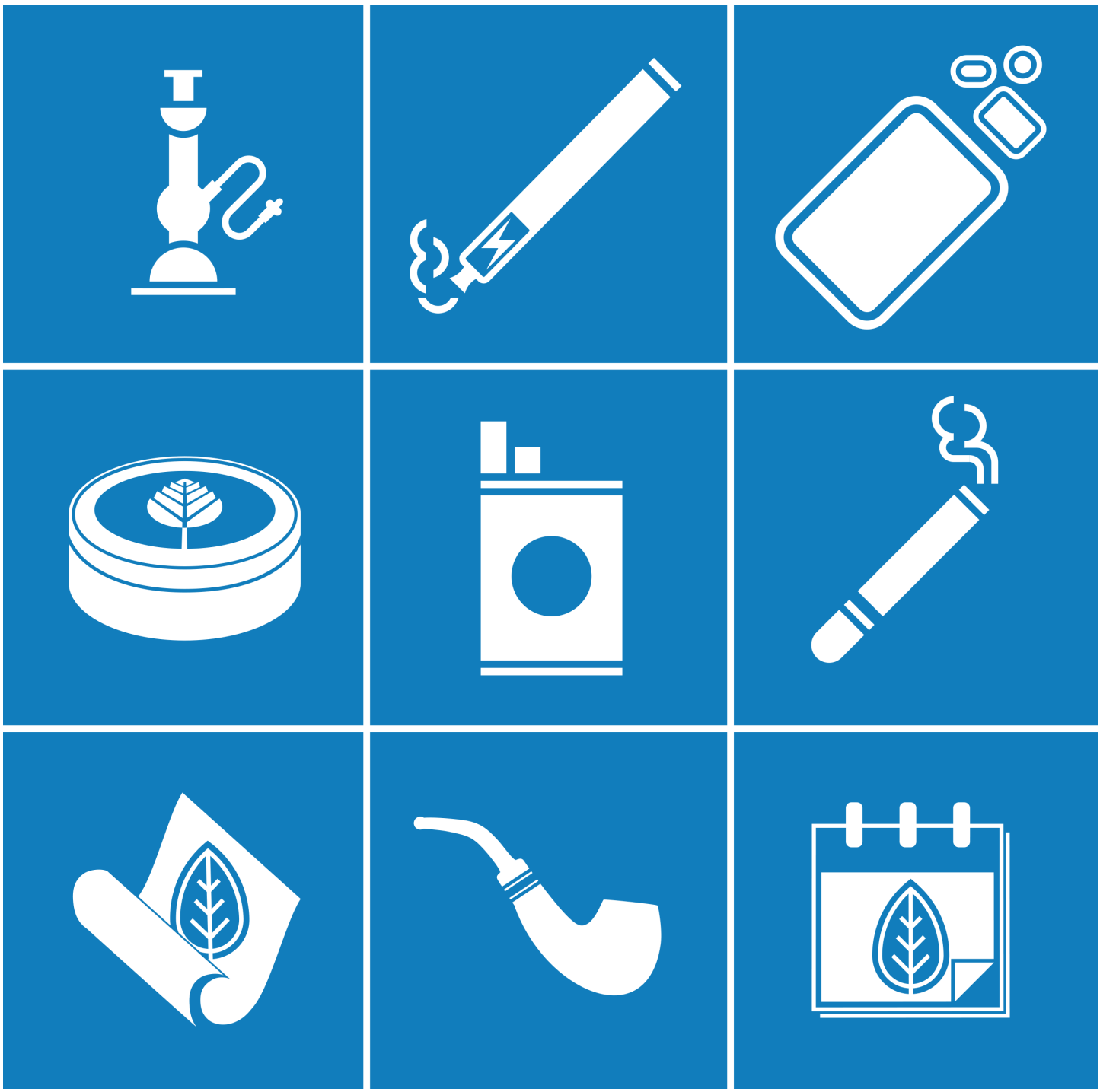
# The Facts on the FDA's New Tobacco Rule



The FDA regulates all tobacco products, including (as shown): hookah, e-cigarettes, dissolvables, smokeless tobacco, cigarettes, all cigars, roll-your-own tobacco, pipe tobacco, and future tobacco products that meet the statutory definition of a tobacco product.

**Español (/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspanol/ucm507307.htm)**



The U.S. Food and Drug Administration recently finalized a rule that extends its regulatory authority to all tobacco products, including e-cigarettes, cigars, and hookah and pipe tobacco, as part of its goal to improve public health.

“Before this final rule, these products could be sold without any review of their ingredients, how they were made, and their potential dangers,” explains Mitch Zeller, J.D., director of the FDA’s Center for Tobacco Products. “Under this new rule, we’re taking steps to protect Americans from the dangers of tobacco products, ensure these tobacco products have health warnings, and restrict sales to minors.”

Still have questions about this rule? Read on for answers.

### What does this new rule do?

This new rule builds on groundwork that was set close to seven years ago. The FDA has regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products since June 2009, after Congress passed and the President signed the Family Smoking Prevention and Tobacco Control Act. This Act gave the agency authority to regulate the manufacturing, distribution, and marketing of tobacco products.

Today, the rule does several things.

It extends the FDA’s regulatory authority to all tobacco products, including e-cigarettes—which are also called electronic cigarettes or electronic nicotine delivery systems (ENDS)—all cigars (including premium ones), hookah (also called waterpipe tobacco), pipe tobacco, nicotine gels, and dissolvables that did not previously fall under the FDA’s authority.

It requires health warnings on roll-your-own tobacco, cigarette tobacco, and certain newly regulated tobacco products and also bans free samples. In addition, because of the rule, manufacturers of newly regulated tobacco products that were not on the market as of February 15, 2007, will have to show that products meet the applicable public health standard set by the law. And those manufacturers will have to receive marketing authorization from the FDA.

The new rule also restricts youth access to newly regulated tobacco products by: 1) not allowing products to be sold to those younger than 18 and requiring age verification via photo ID; and 2) not allowing tobacco products to be sold in vending machines (unless in an adult-only facility).

Finally, it gives a foundation for future FDA actions related to tobacco.

### Why did the FDA take this action?

The FDA’s goal is to protect Americans from tobacco-related disease and death. Tobacco use is a major threat to public health.

It's important to note that FDA regulation of these products does not mean they are safe to use. But before this rule, there was no federal law to stop retailers from selling e-cigarettes, hookah, or cigars to youth under age 18. There has been a major drop in the use of traditional cigarettes among youth over the past decade, but their use of other tobacco products is rising. Current e-cigarette use among high school students has skyrocketed from 1.5 percent in 2011 to 16 percent in 2015 (a more than 900 percent increase) and hookah use has risen significantly, according to a survey supported by the FDA and the Centers for Disease Control and Prevention.

This rule allows the FDA to protect youth by restricting their access to tobacco products.

**What product characteristics will the FDA review?**

The tobacco product review process allows the FDA to evaluate important factors such as ingredients, product design and health risks, as well as products' appeal to youth and non-users.

**What's the timeline?**

The FDA expects that manufacturers will continue selling their products for up to two years while they submit—and an additional year while the FDA reviews—a new tobacco product application.

The FDA will issue an order to give marketing authorization where appropriate. Otherwise, the product will face FDA enforcement.

**What's the bottom line?**

The rule will help prevent young people from starting to use these products, help consumers better understand the risks of using these products, prohibit false and misleading product claims, and prevent new tobacco products from being marketed unless a manufacturer demonstrates that the products meet the relevant public health standard.

**But aren't e-cigarettes safer than regular cigarettes? And what about the burden on small businesses?**

The FDA recognizes that some tobacco products have the potential to be less harmful than others. But more evidence is needed. The agency is exploring this issue with respect to tobacco regulation.

The FDA believes that this new technology has both potential benefits and risks. If certain products, such as e-cigarettes, have reduced toxicity compared to conventional cigarettes; encourage current smokers to switch completely; and/or are not widely used by youth, they may have the potential to reduce disease and death. But if any product prompts young people to become addicted to nicotine, reduces a person's interest in quitting cigarettes, and/or leads to long-term usage with other tobacco products, the public health impact could be negative.

The FDA encourages manufacturers to explore product innovations that would maximize potential benefits and minimize risks. The final rule allows the FDA to further evaluate and assess the impact of these products on the health of both users and non-users. And it lets the FDA regulate the products based on the most current scientific knowledge.

The FDA considered all manufacturers, including small businesses, when finalizing this rule. That's why the agency is allowing additional time for small-scale tobacco product manufacturers to comply with certain provisions.

**So which products can help me quit using tobacco?**

The FDA has approved a variety of products as cessation aids to help reduce your dependence on nicotine. Products include nicotine gum, nicotine skin patches, nicotine lozenges, nicotine oral inhaled products, and nicotine nasal spray as well as non-nicotine medications called varenicline and bupropion.

You can also get free help quitting by calling 1-800-QUIT-NOW or by visiting **www.smokefree.gov (https://smokefree.gov/)**.

*June 16, 2016*

**back to top**

**More in Consumer Updates (/ForConsumers/ConsumerUpdates/default.htm)**

**Animal & Veterinary (/ForConsumers/ConsumerUpdates/ucm149147.htm)**

**Children's Health (/ForConsumers/ConsumerUpdates/ucm047364.htm)**

**Cosmetics (/ForConsumers/ConsumerUpdates/ucm149191.htm)**

**Dietary Supplements (/ForConsumers/ConsumerUpdates/ucm153239.htm)**

**Drugs (/ForConsumers/ConsumerUpdates/ucm149195.htm)**

**Food (/ForConsumers/ConsumerUpdates/ucm149202.htm)**

**Medical Devices (/ForConsumers/ConsumerUpdates/ucm149209.htm)**

**Nutrition (/ForConsumers/ConsumerUpdates/ucm244206.htm)**

**Radiation-Emitting Products (/ForConsumers/ConsumerUpdates/ucm149210.htm)**

**Tobacco Products (/ForConsumers/ConsumerUpdates/ucm237634.htm)**

**Vaccines, Blood & Biologics (/ForConsumers/ConsumerUpdates/ucm149184.htm)**

Articulos en Espanol (/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspanol/default.htm)