FDA NEWS RELEASE

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FDA takes significant steps to protect Americans from dangers of tobacco through new regulation

Rule extending oversight to all tobacco products, including e-cigarettes, allows agency to address public health concerns such as youth access to tobacco products.

Today, the U.S. Food and Drug Administration finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others. This historic rule helps implement the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009 and allows the FDA to improve public health and protect future generations from the dangers of tobacco use through a variety of steps, including restricting the sale of these tobacco products to minors nationwide.

"We have more to do to help protect Americans from the dangers of tobacco and nicotine, especially our youth. As cigarette smoking among those under 18 has fallen, the use of other nicotine products, including e-cigarettes, has taken a drastic leap. All of this is creating a new generation of Americans who are at risk of addiction," said HHS Secretary Sylvia Burwell. "Today's announcement is an important step in the fight for a tobacco-free generation – it will help us catch up with changes in the marketplace, put into place rules that protect our kids and give adults information they need to make informed decisions."

Tobacco use is a significant public health threat. In fact, smoking is the leading cause of preventable disease and death in the United States and responsible for 480,000 deaths per year. While there has been a significant decline in the use of traditional cigarettes among youth over the past decade, their use of other tobacco products continues to climb. A recent survey supported by the FDA and the Centers for Disease Control and Prevention shows current e-cigarette use among high school students has skyrocketed from 1.5 percent in 2011 to 16 percent in 2015 (an over 900 percent increase) and hookah use has risen significantly. In 2015, 3 million middle and high school students were current e-cigarette users, and data showed high school boys smoked cigars at about the same rate as cigarettes. Additionally, a joint study by the FDA and the National Institutes of Health shows that in 2013-2014, nearly 80 percent of current youth tobacco users reported using a flavored tobacco product in the past 30 days – with the availability of appealing flavors consistently cited as a reason for use.

Before today, there was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco or cigars to people under age 18. Today's rule changes that with provisions aimed at restricting youth access, which go into effect in 90 days, including:

- Not allowing products to be sold to persons under the age of 18 years (both in person and online);

- Requiring age verification by photo ID;
- Not allowing the selling of covered tobacco products in vending machines (unless in an adult-only facility); and
- Not allowing the distribution of free samples.

The actions being taken today will help the FDA prevent misleading claims by tobacco product manufacturers, evaluate the ingredients of tobacco products and how they are made, as well as communicate their potential risks.

Today's rule also requires manufacturers of all newly-regulated products, to show that the products meet the applicable public health standard set forth in the law and receive marketing authorization from the FDA, unless the product was on the market as of Feb. 15, 2007. The tobacco product review process gives the agency the ability to evaluate important factors such as ingredients, product design and health risks, as well as their appeal to youth and non-users.

Under staggered timelines, 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 granting marketing authorization where appropriate; otherwise, the product will face FDA enforcement.

For decades, the federal government and the public health community have fought to protect people from the dangers of tobacco use. Since the first Surgeon General's report on Smoking and Health in 1964, which warned Americans about the risks associated with smoking, significant progress has been made to reduce smoking rates among Americans. In fact, tobacco prevention and control efforts have saved at least 8 million lives in the last 50 years, according to the 2014 Surgeon General's Report on the Health Consequences of Smoking. In 2009, Congress took a historic step in the fight for public health by passing the bipartisan Family Smoking Prevention and Tobacco Control Act (TCA) giving the FDA authority to regulate the manufacturing, distribution and marketing of tobacco products to protect the public health.

Today's action marks a new chapter in the FDA's efforts to end preventable tobacco-related disease and death and is a milestone in consumer protection.

"As a physician, I've seen first-hand the devastating health effects of tobacco use," said FDA Commissioner Robert M. Califf, M.D. "At the FDA, we must do our job under the Tobacco Control Act to reduce the harms caused by tobacco. That includes ensuring consumers have the information they need to make informed decisions about tobacco use and making sure that new tobacco products for purchase come under comprehensive FDA review."

Today's actions will subject all manufacturers, importers and/or retailers of newly-regulated tobacco products to any applicable provisions, bringing them in line with other tobacco products the FDA has regulated under the TCA since 2009.

These requirements include:

- Registering manufacturing establishments and providing product listings to the FDA;

- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring premarket review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

"This final rule is a foundational step that enables the FDA to regulate products young people were using at alarming rates, like e-cigarettes, cigars and hookah tobacco, that had gone largely unregulated," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "The agency considered a number of factors in developing the rule and believes our approach is reasonable and balanced. Ultimately our job is to assess what's happening at the population level before figuring out how to use all of the regulatory tools Congress gave the FDA."

To assist the newly-regulated tobacco industry in complying with the requirements being announced today, the FDA is also publishing several other regulatory documents that provide additional clarity, instructions and/or the FDA's current thinking on issues specific to the newly-regulated products.

For more information:

- Final Rule: [FR LINK]
- Deeming – Extending Authorities to All Tobacco Products: [LINK]

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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