

FOR IMMEDIATE RELEASE:

April 24, 2014

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CORRECTED: Long Awaited FDA Proposal to Regulate E-Cigarettes, Cigars and Other Tobacco Products is an Important Step Forward for Public Health

American Lung Association Calls on Obama Administration Not to Exempt Cigars in Final Rule

NOTE: This corrects "6-12 year olds" in paragraph 12 to read 6-12th graders.

Washington, D.C. (April 24, 2014) – Today, the Food and Drug Administration's (FDA) Center for Tobacco Products issued its long-awaited proposal to regulate e-cigarettes, cigars, little cigars, hookah, pipe tobacco and other tobacco products. The proposed regulation would give FDA basic oversight authority over these unregulated products and require manufacturers to register with FDA; disclose their products' ingredients to the agency; and would prohibit tobacco companies from making health claims without FDA review. The proposed regulation would also establish 18 as the nationwide minimum age for the legal purchase of tobacco products.

One very troubling provision in the proposed regulation could create an exemption for certain types of cigars. The FDA seeks public comment on this carve-out provision.

"The American Lung Association welcomes the long-awaited release of this critical step to extend FDA's basic oversight over all tobacco products," said Harold Wimmer, National President and CEO of the American Lung Association. "The years of delay have allowed e-cigarette use among youth to double. We call upon the Obama Administration and the FDA to finalize this proposal by the end of this year and ensure that it applies to all tobacco products."

The 2009 Family Smoking Prevention and Tobacco Control Act does not require FDA to regulate all tobacco products in the exact same manner. Instead, the Tobacco Control Act requires the agency to enact measures that are "appropriate for the protection of public health."

"Any exemption for any kind of tobacco product proven to cause lung and heart disease and cancer is unacceptable," added Wimmer. "FDA must have basic authority over all tobacco products in order to protect public health and the health of our children. Ending the tobacco epidemic can only happen if the Obama Administration acts aggressively and broadly to protect American women, men and children from all tobacco products – not give a sweetheart deal to the cigar industry."

Proposal Would Otherwise Give FDA Basic Oversight Authority Over Unregulated Products

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) requires the new Center for Tobacco Products to take actions that are "appropriate for the protection of public health." This regulation proposes to extend basic authorities found in the Tobacco Control Act to all other tobacco products, including:

- Registration by all manufacturers with FDA, including a list of all tobacco products they sell
- Disclosure of ingredients by manufacturers to FDA
- Prohibit the sales of tobacco products to anyone under the age of 18

- Eliminate free sampling of all tobacco products
- Good manufacturing practice requirements
- Premarket review for any “new” tobacco product
- Premarket review of any product wishing to make a “modified risk or harm” claim

In addition, user fees, which pay for all of FDA’s tobacco work, would be required of certain classes of products.

While all states have laws that require people to be at least 18 years old to buy cigarettes and most other tobacco products, about half of all states do not have a similar law in place requiring a minimum age to buy e-cigarettes. Today’s proposal would end these loopholes for e-cigarettes.

Tobacco Industry Exploited Delay

When Congress passed the Tobacco Control Act, it created FDA’s Center for Tobacco Products and gave it immediate authority over cigarettes, smokeless and roll-your-own tobacco products. Congress gave authority to the agency to assert jurisdiction over other tobacco products, which FDA is finally doing today. FDA initially announced its intent to assert jurisdiction over other tobacco products in 2010, and in [April of 2011](#) announced its plan to include e-cigarettes as well.

The tobacco industry wasted no time in exploiting the loopholes in federal oversight of tobacco products – setting its sights on unregulated products, especially e-cigarettes and cigars, to addict the latest generation of kids to nicotine and its deadly products.

The cigar industry has taken advantage of the lag in FDA oversight of these products. In August 2012, CDC released a series of studies showing a rapid increase in use of cigars, including large cigars. CDC found that while cigarette use declined 33 percent from 2000-2011, the use of large cigars increased 233 percent. Additional CDC studies showed that current rates of cigar and smokeless tobacco use—particularly among high school boys—nearly match the rates of cigarette smoking, and that cigar use among African American high school students increased from 7.1 percent in 2009 to 16.7 percent in 2012.

In September 2013, the Centers for Disease Control and Prevention released new data showing an alarming increase in e-cigarette use among middle school and high school students in the U.S. From 2011-2012, the number of students in grades 6-12 reporting having ever used an e-cigarette doubled from 3.3 percent to 6.8 percent. Recent use of e-cigarettes among 6-12th graders increased from 1.1 percent to 2.1 percent.

“Once FDA finalizes this regulation, it is imperative the agency move forward with a product standard to end the sales of all candy- and fruit-flavored products, like Cap’n Crunch and Atomic Fireball,” stated Wimmer. “FDA must use its authority aggressively to crack down on this industry, which markets its products to our nation’s children.”

Aggressive Action from FDA will be Critical to Reducing Nation’s Leading Cause of Preventable Death

January marked the 50th anniversary of the landmark 1964 Surgeon General’s report on smoking and health. On January 17, the U.S. Surgeon General released a new report, “The Health Consequences of Smoking—50 Years of Progress,” which found tobacco is even deadlier than it was 50 years ago. The report also highlighted the critical need for FDA to aggressively use its authority to require changes in the sales, marketing and manufacture of tobacco products.

“We will continue to thoroughly review the proposal and provide detailed comments in an attempt to improve the final rule’s public health protection,” said Wimmer. “But any exemption for any tobacco product is unacceptable.”

For the last four years, the FDA failed to keep pace with the increasingly aggressive marketing and product development by the portions of the tobacco industry unregulated by FDA. In the American Lung Association’s [“State of Tobacco Control 2014”](#) report, the FDA received a D grade for the Obama Administration’s failure to regulate e-cigarettes, cigars and other unregulated tobacco products.

In January, the American Lung Association and our public health and medical partners called for bold action by all levels of government to achieve three bold goals:

- Reduce smoking rates, currently at about 18 percent, to less than 10 percent within 10 years;
- Protect all Americans from secondhand smoke within five years; and
- Ultimately eliminate the death and disease caused by tobacco use.

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About the American Lung Association

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