

Feds announce final e-cigarette rule that nearly bans them



© Ed Andrieski/AP Photo FILE - In this March 2, 2011, file photo, a clerk holds an electronic cigarette and the filter end that holds the liquid nicotine solution at an E-Smokes store in Aurora, Colo. Increasingly popular e-cigarettes and cigar varieties...

Electronic cigarettes and premium cigars will now be regulated the same way as tobacco cigarettes and regular cigars, according to a new federal rule issued on Thursday.

Under the rule, the U.S. Food and Drug Administration would have to approve all tobacco products not currently regulated that hit stores after February 2007. The e-cigarette industry was virtually non-existent before then.

Premium, hand-rolled cigars would also be included in the new regulation. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements.

The Tobacco Control Act of 2009 sets February 15, 2007, as the latest date by which all tobacco

products would have to have to be grandfathered in. Mitch Zeller, head of the FDA's Center for Tobacco Products, has said publicly that he couldn't choose a later date, although industry officials disagree.

That means nearly all every e-cigarette on the market — and every different flavor and nicotine level — would require a separate application for federal approval. Each application could cost \$1 million or more, says Jeff Stier, an e-cigarette advocate with the National Center for Public Policy Research and industry officials.

An amendment to appropriations legislation working its way through the House would change the date so more e-cigarettes would be grandfathered in.

The proposed rule was released more than two years ago in April 2014 and the final rule gives the industry two additional years to comply. The industry will have had "plenty of time to submit their applications," says Robin Koval, CEO of the Truth Initiative, an anti-tobacco health group.

Koval says "it's perfectly reasonable" that people should know what's in something that "you inhale into your lungs."

"All of these products should have to be held to some standard," says Koval.

Department of Health and Human Services Secretary Sylvia Burwell and FDA Administrator Robert Califf, a physician, were scheduled to brief reporters at 10:30 a.m. Thursday.

Industry experts say treating e-cigarettes, which don't contain tobacco, the same as cigarettes could lead to such onerous and costly approval that all but the largest tobacco companies would be forced out of the market — and possibly those companies too.

The Tobacco Control Act requires the FDA to use science to weigh the potential benefits of e-cigarettes against any potential health risk, for both the individual users and the whole population, which Stier says would be all but impossible.

That could force e-cigarette smokers back to regular cigarettes, he says.

E-cigarettes help people trying to quit smoking, says Patricia Kovacevic, general counsel and chief compliance officer at e-cigarette manufacturer Nicopure. She and other e-cigarette advocates cited a Royal College of Physicians' report last week that showed e-cigarettes' benefits.

Lawmakers have to address the possible adverse health effects of e-cigarettes, she says, but the rule doesn't account for the comparative benefits of e-cigarettes over regular tobacco products for improving overall public health.

Koval agrees that e-cigarettes "are dramatically less harmful" than regular cigarettes. "But they're not without harm," she says. "It would be hard to make a product more harmful or toxic than cigarettes."

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