

E-cigarettes violate drug rules: FDA

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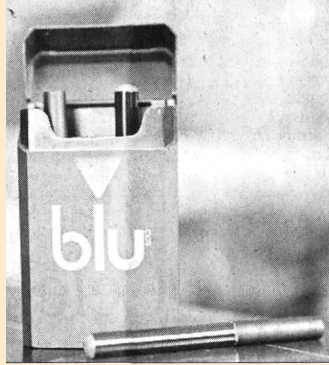
BLOOMBERG

ELECTRONIC cigarettes sold in the U.S. are being marketed illegally as smoking-cessation aids, the Food and Drug Administration said.

E-cigarettes and related products sold by five closely held companies require approval as drugs or medical devices because they're promoted to help smokers stop or reduce use of regular cigarettes, the FDA said in warning letters posted to day on the agency's website. To sell the products, companies must conduct animal and human studies and apply for FDA clearance, the agency said in a separate letter to the Electronic Cigarette Association, a Washington-based industry group.

E-cigarettes are metallic tubes filled with a vaporized liquid nicotine mixture. While the devices mimic the look and feel of traditional cigarettes, they don't contain tobacco or produce smoke. The FDA in February won a temporary delay of a U.S. judge's ruling that the agency lacks authority to regulate the products as drugs or medical devices and must allow them to be imported. The case is scheduled for a Sept. 23 hearing.

"Although these products are frequently marketed to help consumers quit smoking, the FDA has not evaluated them for safety or effectiveness," Michael Levy, director of the agency's Division



of New Drugs and Labeling Compliance, said today on a conference call.

Five Companies

The warning letters were sent to Gamucci America, a unit of Smokey Bayou Inc. in Jacksonville, Florida; E-Cig Technology Inc. in Las Vegas; Ruyan America Inc. in Minneapolis; Johnson Creek Enterprises LLC in Johnson Creek, Wis-

consin; and E-CigaretteDirect LLC in Parker, Colorado. The companies have 15 days to respond.

The FDA will evaluate those responses before deciding whether the products should be taken off the market, Levy said.

Ruyan America hasn't imported or sold any products containing nicotine since May 2009, the company's president, Bill Bartkowski, said today in a telephone interview.

"There seem to be references in the letter to a variety of things that are a little bit dated and no longer accurate," Bartkowski said. "We hope to address that in our response to the FDA."

E-Cig Technology, Johnson Creek and E-CigaretteDirect didn't immediately respond to e-mails sent through contact procedures on their websites. Smokey Bayou didn't immediately respond to a voicemail message left at a listed phone number. The FDA should hold e-cigarettes to the same standards for safety and effectiveness as other drugs, including nicotine replacement therapies, said Matthew Myers, president of the nonprofit Campaign for Tobacco-Free Kids, in Washington.

"Electronic cigarettes should be regulated to protect public health before they are permitted to be sold to consumers," Myers said today in an e-mail. Smoking-cessation products approved by the FDA include prescription nasal sprays and over-the-counter gums, patches and lozenges.