

US says electronic cigarettes must get government approval

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So-called electronic cigarettes cannot be sold in the United States without getting regulatory approval, the Food and Drug Administration said Thursday.

The FDA sent a warning letter to five distributors of the product saying they have made "unsubstantiated claims" for the [nicotine](#) delivery devices and that the makers need to prove e-cigarettes are safe and effective.

Electronic cigarettes are battery-powered devices that have no tobacco but deliver a dose of nicotine to the user, while producing water vapor that looks like smoke. Used in a number of countries, they are promoted as a way to quit smoking.

The FDA said the devices deliver a drug and thus must get approval to show it is safe and effective and that the makers must demonstrate safeguards in the manufacturing process.

"FDA has determined that the electronic cigarette products addressed in the warning letters to the distributors, and similar products, are subject to FDA regulation as drugs," said the letters sent to the distributors.

Under US regulations, FDA said, "a company cannot claim that its drug can treat or mitigate a disease, such as [nicotine addiction](#), unless the drug's safety and effectiveness have been proven. Yet all five companies claim without FDA review of relevant evidence that the products help

users quit [smoking cigarettes](#)."

The agency sent warning letters to five distributors: E-CigaretteDirect LLC, Ruyan America Inc., Gamucci America, E-Cig Technology Inc. and Johnson's Creek Enterprises LLC.

It also sent a letter to the Electronic Cigarette Association saying the agency "intends to regulate electronic cigarette and related products in a manner consistent with its mission of protecting the public health."

"FDA invites electronic cigarette firms to work in cooperation with the agency toward the goal of assuring that electronic cigarettes sold in the United States are lawfully marketed," said an FDA letter to the trade group for the industry.

The agency had previously warned consumers that many [electronic cigarettes](#) contained dangerous chemicals and it has taken steps to block the import of many such products.

The new warnings indicate a more aggressive position on e-cigarettes, which are intended as a replacement for cigarettes and cigars.

The association based in Washington could not be immediately reached for comment.

One of the distributors cited, Ruyan America, no longer sells the product and does not intend to until regulatory issues are resolved, said company president Bill Bartkowski.

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