



FDA Warns of Health Risks Posed by E-Cigarettes

The Food and Drug Administration (FDA) has joined other health experts to warn consumers about potential health risks associated with electronic cigarettes.

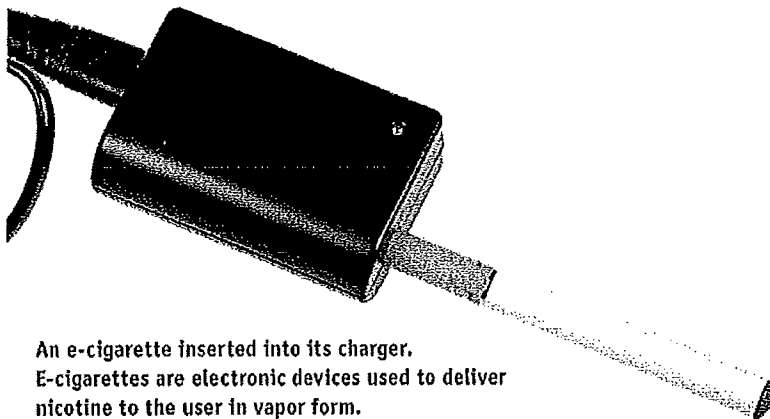
Also known as "e-cigarettes," electronic cigarettes are battery-operated devices designed to look like and to be used in the same manner as conventional cigarettes.

Sold online and in many shopping malls, the devices generally contain cartridges filled with nicotine, flavor, and other chemicals. They turn nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

"The FDA is concerned about the safety of these products and how they are marketed to the public," says Margaret A. Hamburg, M.D., commissioner of food and drugs.

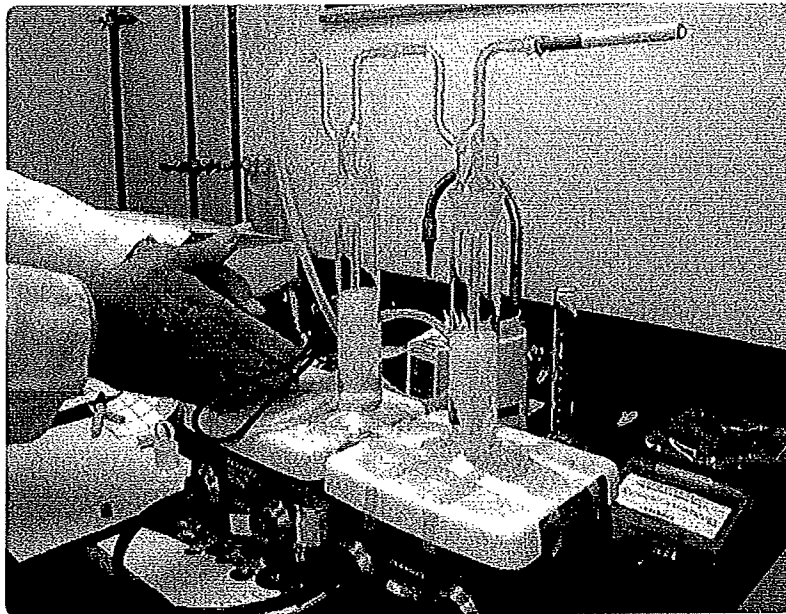
The agency is concerned that

- e-cigarettes can increase nicotine addiction among young people and may lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death
- the products may contain ingredients that are known to be toxic to humans
- because clinical studies about the safety and efficacy of these products for their intended use have not been



An e-cigarette inserted into its charger. E-cigarettes are electronic devices used to deliver nicotine to the user in vapor form.

FDA



Air is drawn through an e-cigarette during a laboratory procedure that simulates a smoker taking a puff. The resulting vapor is tested.

FDA

submitted to FDA, consumers currently have no way of knowing

- whether e-cigarettes are safe for their intended use
- about what types or concentrations of potentially harmful chemicals, or what dose of nicotine they are inhaling when they use these products

The potential health risks posed by the use of e-cigarettes were addressed in a July 22, 2009, phone conference between Joshua M. Sharfstein, M.D., principal deputy commissioner of food and drugs; Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium; Jonathan Samet, M.D., director of the University of Southern California's Institute for Global Health; and Matthew T. McKenna, M.D., director of the Office on Smoking and Health at the national Centers for Disease Control and Prevention.

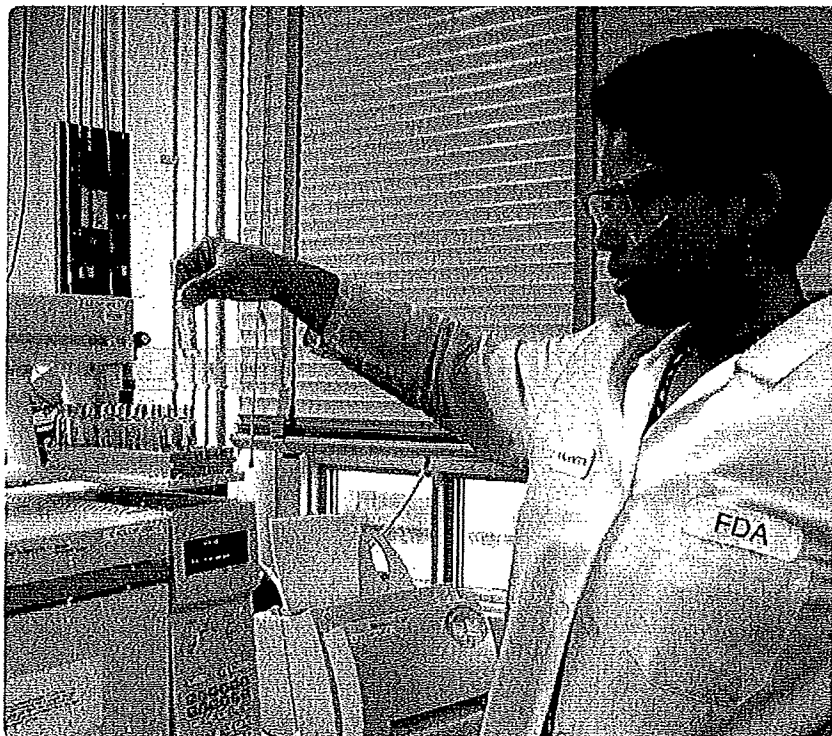
Conference participants stressed the importance of parents being aware of the health and marketing concerns associated with e-cigarettes. It was stated that parents may want to tell their children and teenagers that these products are not safe to use.

Of particular concern to parents is that e-cigarettes are sold without any legal age restrictions, and are available in different flavors (such as chocolate, strawberry and mint) which may appeal to young people.

In addition, the devices do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes.

During the phone conference, which was shared with the news media, FDA announced findings from a laboratory analysis that indicates that electronic cigarettes expose users to harmful chemical ingredients.

FDA's Division of Pharmaceutical Analysis—part of the agency's Center for Drug Evaluation and Research—analyzed the ingredients in a small sample of cartridges from two leading brands of e-cigarette samples.



An FDA chemist uses a device set to the same temperature as an activated e-cigarette. This helps determine what might be inhaled by users of these products.

One sample was found to contain diethylene glycol, a toxic chemical used in antifreeze. Several other samples were found to contain carcinogens, including nitrosamines.

Agency Actions

FDA has been examining and detaining shipments of e-cigarettes at the border and has found that the products it has examined thus far meet the definition of a combination drug device product under the Federal Food, Drug, and Cosmetic Act.

The agency has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court.

FDA is planning additional activities to address its concerns about electronic cigarettes.

Meanwhile, health care professionals and consumers may report seri-

ous adverse events or product quality problems with the use of e-cigarettes to FDA through the MedWatch program, either online at www.fda.gov/Safety/MedWatch/default.htm or by phone at 1-800-FDA-1088.

This article appears on FDA's Consumer Updates page (www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

For More Information

FDA Press Release
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm

E-Cigarettes: FDA Web page
www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm