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FDA NEWS RELEASE

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FDA and Public Health Experts Warn About Electronic Cigarettes

The U.S. Food and Drug Administration today announced that a laboratory analysis of electronic cigarette samples has found that they contain carcinogens and toxic chemicals such as diethylene glycol, an ingredient used in antifreeze.

Electronic cigarettes, also called "e-cigarettes," are battery-operated devices that generally contain cartridges filled with nicotine, flavor and other chemicals. The electronic cigarette turns nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user.

These products are marketed and sold to young people and are readily available online and in shopping malls. In addition, these products do not contain any health warnings comparable to FDA-approved nicotine replacement products or conventional cigarettes. They are also available in different flavors, such as chocolate and mint, which may appeal to young people.

Public health experts expressed concern that electronic cigarettes could increase nicotine addiction and tobacco use in young people. Jonathan Winickoff, M.D., chair of the American Academy of Pediatrics Tobacco Consortium and Jonathan Samet, M.D., director of the Institute for Global Health at the University of Southern California, joined Joshua Sharfstein, M.D., principal deputy commissioner of the FDA, and Matthew McKenna, M.D., director of the Office of Smoking and Health for the Centers for Disease Control and Prevention, to discuss the potential risks associated with the use of electronic cigarettes.

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

Because these products have not been submitted to the FDA for evaluation or approval, at this time the agency has no way of knowing, except for the limited testing it has performed, the levels of nicotine or the amounts or kinds of other chemicals that the various brands of these products deliver to the user.

The FDA's Division of Pharmaceutical Analysis analyzed the ingredients in a small sample of cartridges from two leading brands of electronic cigarettes. In one sample, the FDA's analyses detected diethylene glycol, a chemical used in antifreeze that is toxic to humans, and in several other samples, the FDA analyses detected carcinogens, including nitrosamines. These tests indicate that these products contained detectable levels of known carcinogens and toxic chemicals to which users could potentially be exposed.

The FDA has been examining and detaining shipments of e-cigarettes at the border and 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 FDA has been challenged regarding its jurisdiction over certain e-cigarettes in a case currently pending in federal district court. The agency is also planning additional activities to address its concerns about these products.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of e-cigarettes to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

- Online: http://www.fda.gov/Safety/MedWatch/default.htm[1]
- Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm[2] and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

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