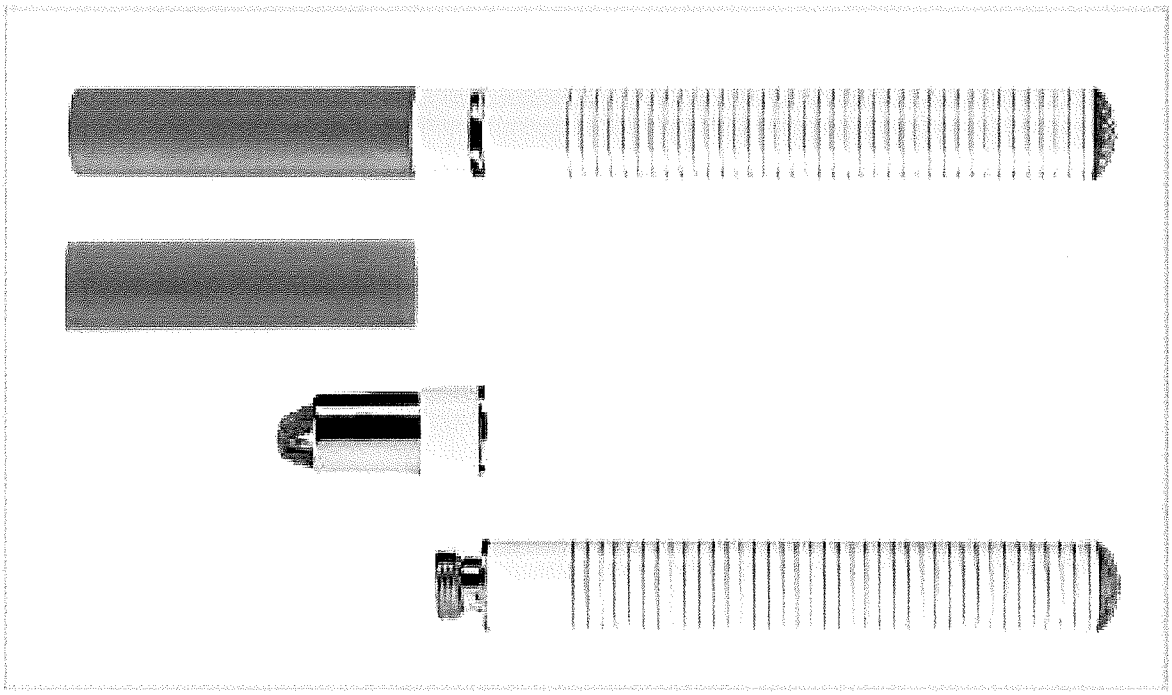
U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Electronic Cigarettes (e-Cigarettes)

What are electronic cigarettes?

Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals. They turn chemicals, including highly addictive nicotine, into an aerosol that is inhaled by the user.



Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks.

E-cigarettes have not been fully studied, so consumers currently don't know:

- the potential risks of e-cigarettes when used as intended,
- how much nicotine or other potentially harmful chemicals are being inhaled during use, or
- whether there are any benefits associated with using these products.

Additionally, it is not known whether e-cigarettes may lead young people to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death.

FDA Regulation of e-Cigarettes

Only e-cigarettes that are marketed for therapeutic purposes are currently regulated by the FDA Center for Drug Evaluation and Research (CDER). Currently, the FDA Center for Tobacco Products (CTP) regulates

- cigarettes,
- cigarette tobacco,
- roll-your-own tobacco, and
- smokeless tobacco.

FDA has issued a proposed rule that would extend the agency's tobacco authority to cover additional products that meet the legal definition of a tobacco product, such as e-cigarettes. FDA's **Extending Authorities to Additional Tobacco Products webpage (/TobaccoProducts/Labeling/ucm388395.htm)** offers more information on the proposed rule, including how to submit comments.

For more information on current regulation:

- **Tobacco Product Regulation (/TobaccoProducts/ResourcesforYou/ucm335294.htm)**
- **Nicotine-Containing Products (/Drugs/GuidanceComplianceRegulatoryInformation/ucm345928.htm)**

How to Comment

To comment on the proposed rule:

1. **Read the proposed rule (http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-20870)**.
2. Through August 8, 2014, **go to Regulations.gov to submit comments (http://www.regulations.gov/#!submitComment;D=FDA-2014-N-0189-20870)**.

Comment Now (http://www.regulations.gov/#!submitComment;D=FDA-2014-N-0189-20870)

eCigarettes and Adverse Events

What is an Adverse Event?
An adverse event is an undesirable side effect or unexpected health or product quality problem that an individual believes was caused by the use of a tobacco product.

Reporting an Adverse Event
Anyone can report an adverse event to the FDA. In fact, these reports help us identify safety concerns with tobacco products that could cause health or safety problems beyond those normally associated with tobacco product use.

Please report adverse events with e-cigarettes via:

- The **HHS Safety Reporting Portal (https://www.safetyreporting.hhs.gov/)** or
- By calling 1-800-FDA-1088

Please send other information or inquiries regarding e-cigarettes to:

- 1-877-CTP-1373 or
- **AskCTP@fda.hhs.gov (mailto:AskCTP@fda.hhs.gov)**

Adverse Event Reports for e-Cigarettes

We regularly receive voluntary reports[1] of adverse events involving e-cigarettes from consumers, health professionals and concerned members of the public. The adverse events described in these reports have included hospitalization for illnesses such as

- pneumonia,
- congestive heart failure,
- disorientation,
- seizure,
- hypotension, and
- other health problems.

Whether e-cigarettes caused these reported adverse events is unknown. Some of the adverse events could be related to a pre-existing medical condition or to other causes that were not reported to FDA. You can review the adverse event reports for e-cigarettes that were voluntarily reported to FDA from 6/22/2009 to 3/12/2014 at the **CTP FOIA Electronic Reading Room (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm221165.htm)**.

1. Under the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, FDA may accept voluntarily submitted information related to tobacco products, even if some of the information concerns tobacco products that are not yet regulated by FDA. **(back)**