

Problems with E-Cigarettes, Vape Products, Hookah, Cigarettes or Tobacco? Tell FDA

Are you using a tobacco product—from e-cigs to cigars and cigarettes, hookah to smokeless—that you believe is defective or is causing an unexpected health problem? Does it have a strange taste or smell?

The U.S. Food and Drug Administration (FDA) wants to hear from you—and has updated the online tool you can use to report a problem (<https://www.safetyreporting.hhs.gov>).

The Department of Health and Human Services' Safety Reporting Portal (SRP) provides a standard-

ized way for consumers, health care professionals, manufacturers, and clinical investigators to let FDA know about an unexpected health or safety issue with a tobacco product.

"There is no known safe tobacco product, but FDA can play a role in helping prevent certain unexpected health consequences," says Ii-Lun Chen, M.D., director of the Division of Individual Health Science in the Office of Science at FDA's Center for Tobacco Products. "FDA wants to prevent certain unexpected health consequences that could occur from defective tobacco products, as well as health or safety problems beyond those typically associated with tobacco product use."

You may submit reports about all tobacco products, including cigarettes, tobacco used for roll-your-own cigarettes, other smoking tobacco, cigars, smokeless tobacco, electronic cigarettes, hookah (water-pipe), and any other product made or derived from tobacco that is intended for human consumption, including components and parts of tobacco products.

What to Report

As part of its charge to protect public health and reduce harm from tobacco products, FDA is interested in reports from consumers about tobacco products that are damaged, defective, or contaminated. These

The portal is designed to be user-friendly with the instructions and questions leading the reporter through each reporting section.

reports could identify concerns that range from cigarettes containing mold to a tobacco product that just smells or tastes wrong.

FDA also wants to know if tobacco product users have experienced an unexpected health or other safety problem that they believe has been caused by use of a particular product. These could include:

- reports of fire caused by tobacco product use
- burns or other injuries
- accidental or unintended exposure of children
- allergic reactions, poisonings and other toxicities
- an unusual reaction in a long-time user

When filling out the online questions in the SRP, reporters can provide information on a number of potential types of product and health problems, such as:

- problems using the tobacco product
- tobacco product mix-ups (such as labeling or packaging errors)
- quality problems, such as unexpected appearance, smell or taste; foreign objects in the product or other possible contamination; or a defective or malfunctioning product
- unusual health problems with any category of tobacco product, such as symptoms that are unusual in their type or severity, injuries or burns, or allergic reactions
- pregnancy or fertility problems, harm to children or non-users, including accidental poisoning, choking or breathing tainted air

How to Report

To submit a report on a tobacco product, access the Safety Reporting Portal online (<https://www.safetyreporting.hhs.gov>).

The portal is designed to be user-friendly with the instructions and questions leading the reporter through each reporting section. However, for additional guidance, FDA is developing a series of online modules to help reporters navigate the system. These modules will show how to access and use the portal and show the different sections of the tobacco questionnaires.

Reporters who are unable to submit reports using the electronic system can contact the Center for Tobacco Products at 1-877-CTP-1373 or AskCTP@fda.hhs.gov.

For problems or adverse experiences with nicotine replacement products, such as those that claim to help smokers quit, you should submit reports through MedWatch (<http://www.fda.gov/safety/medwatch/default.htm>).

What FDA Does with Reports

FDA is building a comprehensive tobacco regulation program to ensure all tobacco products have an appropriate level of regulatory oversight. One part of this process includes understanding the types of adverse experiences of tobacco product users and non-users who are exposed to tobacco products.

FDA reviews and evaluates reports and may take steps, as appropriate, to ensure that the public health is protected. The agency does not routinely contact people who submit reports to

the Safety Reporting Portal to discuss their reports or the outcome of FDA review. However, if a person provides contact information, FDA may sometimes request additional information.

FDA cannot provide individual advice to consumers. If you have an issue that requires medical attention, contact your health care professional.

The Freedom of Information Act (FOIA) requires federal agencies to disclose records requested in writing by any person. FDA posts frequently requested adverse experience reports. The posted reports from June 22, 2009, to March 12, 2014, are available in the CTP FOIA Electronic Reading Room (<http://www.fda.gov/TobaccoProducts/AboutCTP/ucm221165.htm>). (Note that FDA removes identifying information of the person submitting the report before posting these records.)

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html