

Activity Outline
FDA Grand Rounds: Electrical Safety in CTP Regulated Products
April 8, 2021
Virtual

Activity Coordinator:

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Series Description

The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description

Battery-related injury and damage reports associated with electronic nicotine delivery systems (ENDS; e.g., e-cigarettes) increased nearly 100-fold from 2009-2017 despite the likelihood that the voluntary, primarily self-reported incidents were under-reported.1, 2, 3 ENDS battery overheating, fires and explosions (OFE) have resulted in serious, disfiguring or disabling injuries.2, 4 FDA-CTP continues to receive reports of battery-related adverse experiences, including one death.

In response, FDA-CTP conducted public education and outreach, developed an infographic on avoiding tobacco product related OFE, and convened a public workshop and opened a public docket to gather information regarding battery-operated tobacco products electrical safety concerns and risk mitigation.5 That information informed guidances and a proposed rule.6, 7, 8 One guidance provides manufacturers with battery testing (ANSI/CAN/UL 8139 [UL 8139])9 information that could address OFE hazards.6 FDA encourages and supports tobacco products changes to become UL 8139 compliant. FDA provided industry with information that could be included in premarket tobacco product applications that addresses battery-related concerns.7, 8 FDA continues to examine the science to provide support and guidance to tobacco product manufacturers to remove those products that demonstrate high risks, and for manufacturers to develop products that reduce OFE risks to tobacco products consumers.

References

- SM Trigger, B Coleman. Social media mentions of electronic nicotine delivery systems (ENDS) battery-related overheating, fires, and explosions: Findings from a pilot study. *Int J Environ Res Public Health* (2019) 16(8):1308
- CJ Corey, JL Chang, BL Rostron; Electronic nicotine delivery system (ENDS) battery-related burns presenting to US emergency departments.2016; *Injury Epidemiology* (2018) 5:4.
- Battery Safety Concerns in Electronic Nicotine Delivery Systems; Public Workshop; Establishment of a Public Docket; Request for Comments. Docket No. FDA-2016-N-4232 published January 4, 2017 <https://beta.regulations.gov/docket/FDA-2016-N-4232>
- SF Rudy, EL Durmowicz; Electronic nicotine delivery systems: overheating fires and explosions; *Tob Control* (2017) 26:10–18.
- Electronic Cigarette Fires and Explosions in the United States 2009 – 2016; USFA FEMA; July 2017.

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Describe the key electrical risks and hazards associated with battery-operated tobacco products: proximity to body, limited protections and controls, interchangeable cells, high current draw
- Describe how manufacturer compliance with industry standards may reduce electrical risks and hazards
- Explain things users can do to reduce electrical risks and hazards

Target Audience

This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 April 8, 2021

Time	Topic	Speaker
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This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-21-016-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit

Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- ▣ Coyne, Karen, PhD, Associate Director, FDA Center for Tobacco Products *nothing to disclose*
- ▣ Russell, Selena, PhD, Senior Chemist, FDA Center for Tobacco Products *nothing to disclose*

Planning Committee

- ▣ Dinatale, Miriam, Team Leader, Food and Drug Administration *nothing to disclose*
- ▣ Pfundt, Tiffany, PharmD, Pharmacist, FDA *nothing to disclose*

- Wheelock, Leslie, RN, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD *nothing to disclose*

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.