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NEWSLETTER

FDA Workshop on Electronic Nicotine Delivery Systems Highlights Product Safety Concerns

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The U.S. Food and Drug Administration (FDA) held a workshop on Electronic Nicotine Delivery Systems (ENDS) on April 19 and 20, 2017, focusing on the safety of the lithium ion batteries used in the products. The workshop revealed a wide range of manufacturing practices by the industry and the fact that there currently are no safety standards for ENDS.

ENDS are commonly referred as e-cigarettes or "vaping devices." According to one recent study, the ENDS market is anticipated to grow over $50 billion by 2025, at an estimated CAGR of 22.36% from 2015 to 2025.

There were a number of presentations during the workshop highlighting the safety concerns associated with ENDS. Photographs were shown of consumers who have sustained significant injuries as a result of thermal events involving ENDS caused by poorly designed lithium ion batteries. The U.S. Consumer Product Safety Commission (CPSC) also provided an update of their work on lithium ion battery safety and reported on incidents involving ENDS. It was noted that there have been approximately 2,700 reported cases of children ingesting flavored liquid nicotine from ENDS since 2010, including one resulting in death.

Underwriters Laboratories (UL) reported on their newly formed Standards Technical Panel (STP) to cover ENDS activity that will be known as the "Proposed First Edition of the Standard for Electrical Systems of Electronic Cigarettes, UL 8139." The proposed standard is intended to cover the electrical systems in ENDS as well as the lithium ion battery charging systems. UL is expected to seek recognition of the proposed standard as an American National Standard and as a

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A policy statement by the American Academy of Pediatrics states "There is a critical need for ENDS regulation, legislative action, and counter promotion to protect youth. ENDS have the potential to addict a new generation of youth to nicotine and reverse more than 50 years of progress in tobacco control." Two weeks after the FDA workshop, the Trump administration delayed enforcement of a final rule promulgated in 2016 that would have imposed strict FDA oversight on ENDS for the first time. The final rule includes a requirement for new addictiveness warnings and information on what ingredients are contained in ENDS.