

# Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products

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## Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

Additional copies are available online at <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. You may send an e-mail request to [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov) to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products**

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## Guidance for Industry<sup>1</sup>

*This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.*

### I. INTRODUCTION

In this guidance, FDA sets out its compliance policy for premarket review requirements for two types of limited modifications to new tobacco products that were on the market as of August 8, 2016: (1) modifications to battery-operated tobacco products solely to comply with UL 8139; and (2) modifications to liquid nicotine products solely to comply with the Child Nicotine Poisoning Prevention Act of 2015 (CNPPA) flow restrictor requirements for liquid nicotine containers. This compliance policy provides that FDA does not intend to enforce violations of the premarket review requirements against such modified products on the basis of the modifications described in this guidance.<sup>2</sup> In light of their potential safety risks, FDA strongly encourages manufacturers to remove the currently marketed unmodified tobacco products from the market prior to introducing the modified tobacco products to the market.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance was prepared by the Office of Compliance and Enforcement, Office of Science, and Office of Regulations in the Center for Tobacco Products at FDA.

<sup>2</sup> FDA may take enforcement action against these products for violating the premarket review requirements for other reasons.

## II. DISCUSSION

### A. Battery Injury Concerns

From 2009-2017, government agencies and news outlets received reports of injuries and other adverse experiences resulting from the failures of batteries used in electronic nicotine delivery systems (ENDS) products and many more were reported on social media. Despite the likelihood that the true number of incidents was under-reported since the information provided was primarily self-reported and voluntary, all sources identified a growing trend in the number and severity of these incidents. In particular,

- The number of battery-related injury and damage reports associated with ENDS products increased nearly 100-fold during that time period (Ref. 1, 2, 3). With respect to severe injuries since 2014, this increase correlated well with the ENDS product sales trend during that period (Ref. 2).
- ENDS battery fires and explosions have resulted in serious, disfiguring or disabling injuries (Ref. 2, 4).
- Representative sampling of hospital data from 2015-2017 indicates that battery-related injuries associated with ENDS may have been responsible for approximately 678 emergency room visits per year (Ref. 4, 5).

Data received after 2017 indicates that battery-related adverse experiences (AEs) remain a serious issue. FDA recorded 63 battery-related AEs through its Safety Reporting Portal (SRP)<sup>3</sup> between 2017 and mid-2019:

- 2017: 12
- 2018: 42
- 2019<sup>4</sup>: 9

ENDS battery explosions reportedly caused one death in 2018 (Ref. 6) and one death in early 2019 (Ref. 7), although the latter has not been reported to SRP.

UL (formerly known as Underwriters Laboratories) is a global safety certification company. It tests and certifies cells and batteries, chargers, and adapters to UL Standards, as well as key international, national, and regional regulations. UL also contributes to the development and international harmonization of industry safety and performance standards.

UL, along with the U.S. Consumer Product Safety Commission (CPSC), FDA, Health Canada, the American National Standards Institute (ANSI), and industry stakeholders, developed a voluntary industry standard, ANSI/CAN/UL 8139 Standard for Safety for Electrical Systems of Electronic Cigarettes and Vaping Devices (UL 8139),<sup>5</sup> to help manufacturers address battery hazards for electronic cigarettes and other battery-operated tobacco products. The standard

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<sup>3</sup> <https://www.safetyreporting.hhs.gov>

<sup>4</sup> Number of AEs reported January-June 2019

<sup>5</sup> <https://ctech.ul.com/en/news-new/ul-8139-electrical-systems-of-electronic-cigarettes/>

includes all battery chemistries and types. UL 8139 prescribes an approach to evaluate the safety of the electrical, heating, cell, battery, and charging systems of these products. UL 8139 testing includes battery management system evaluation for normal use and foreseeable misuse, mechanical stress testing, accidental activation, compatibility with interconnected systems, and environmental resilience. This testing enhances consumer safety, minimizes battery-related injuries, and mitigates potential risks. As of August 27, 2019, UL has certified 14 e-cigarettes as complying with this standard.

FDA believes that battery-operated tobacco products that comply with UL 8139 have a significantly reduced risk of battery-related AEs.

FDA recognizes that, to comply with UL 8139, manufacturers of battery-operated tobacco products may need to change certain aspects of their product. For battery-operated tobacco products that were on the market as of August 8, 2016 and that are then modified solely and only to the extent necessary to comply with UL 8139, FDA does not intend to initiate enforcement action against such modified products on the basis of these modifications.<sup>6</sup> For such products modified before the submission of a marketing application for the non-modified product, FDA recommends that manufacturers submit a single marketing application that describes both the product that was on the market as of August 8, 2016 and the modified product. For such products modified after the submission of a marketing application for the non-modified product, FDA recommends that manufacturers submit an amendment to the original application that describes the modifications implemented for UL 8139 compliance.<sup>7</sup>

These types of changes to the product to comply with UL 8139 may include but are not limited to: addition of protective circuits and controls; use of a different battery or cell; changes to the wiring, terminals, fuses, or insulation; modifying the product to incorporate 2-step activation; changes to the housing material or construction to meet flammability, crush resistance, water exposure, venting, and temperature test requirements; changes to the battery compartment to prevent user access to the battery or cells; changes to the product design so that venting is away from the mouthpiece; changes to the printed wiring boards to meet flame and temperature ratings; and any changes recommended under UL 8139. Changes to the product that are not necessary to comply with UL 8139, include, but are not limited to: changes to the coil design or other heating element (e.g., number of coils, material, resistance, length, or diameter); changes in the wicking material or amount; changes in the power supplied to the product (i.e., no changes to the number of batteries or cells); and changes to the method of aerosolization of the e-liquid.

## **B. Nicotine Exposure Concerns**

Accidental exposure to e-liquids that contain nicotine can cause toxicity, sometimes resulting in death, particularly in children (Ref. 8, 9, 10, 11). While e-liquids contain numerous chemicals at

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<sup>6</sup> The compliance policy in this guidance provides that FDA does not intend to enforce violations of the premarket review requirements against such modified products solely on the basis of the modifications described in this guidance. FDA may take enforcement action against these products for violating the premarket review requirements for other reasons.

<sup>7</sup> This amendment should refer to the FDA-assigned submission tracking number (STN) provided to the applicant in the Acceptance letter of the original application for the product(s) of which these modifications apply.

various levels, nicotine itself raises the greatest toxicological concern in the context of accidental exposure to the liquid due to its acute toxicity profile and the concentrated amounts found in some e-liquids. In 2018, an expert committee of the National Academies of Sciences, Engineering, and Medicine determined there is “conclusive evidence that oral, dermal, or ocular exposures to e-liquids containing nicotine can cause adverse health effects, including seizures, anoxic brain injury, vomiting, lactic acidosis, and can even be fatal” (Ref. 11).

Infants and children are uniquely vulnerable to acute nicotine toxicity because their natural curiosity and normal gains in mobility and fine motor skills put them at risk for accidental exposure. Additionally, their low body weight and naivety to nicotine make them especially prone to toxicity if exposed.

Epidemiological data from poison control centers have described accidental exposure in children to e-liquids. Between 2001 and 2016, there were 7,707 calls to U.S. poison centers regarding exposure to e-cigarettes and e-liquids for children younger than five years old (Ref. 12). An analysis of calls to U.S. poison centers between 2010 and 2014 indicates that incidents related to e-cigarettes were more likely to involve adverse health effects than those related to cigarettes (Ref. 13). Fatalities in children under three years old after accidental ingestion of liquid nicotine have been reported (Ref. 14, 15, 16, 17).

Effective July 26, 2016, the CNPPA requires that liquid nicotine containers that are “accessible through normal and foreseeable use by a consumer” comply with the “special packaging” standards defined in the Poison Prevention Packaging Act (PPPA). Special packaging is defined as packaging that is “significantly difficult for children under age five to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly” (16 CFR 1700.1). The CNPPA does not apply to sealed, pre-filled, and disposable containers inserted directly into ENDS devices. CPSC staff have issued letters to industry providing that any liquid nicotine product, including existing inventory, covered by the CNPPA must be in special packaging that meets the standards in 16 CFR 1700.15, as determined through testing in accordance with the methods described in 16 CFR 1700.20.

Commonly used types of special packaging, such as child-resistant caps, are reasonably protective when used correctly but require active re-engagement after each use in order to work (Ref. 18). Flow restrictors, on the other hand, are a passive secondary line of protection. Flow restrictors are typically adapters added to the neck of a bottle to limit the release of a liquid and are intended to limit the amount of a liquid substance to which a child can gain access (Ref. 19).

The use of flow restrictors as a secondary barrier may mitigate the risk of toxicity from accidental exposures to e-liquids in children. A study to assess the efficacy of flow restrictors in limiting children’s access to liquid medicines showed that the addition of flow restrictors to bottles decreased the proportion of children who accessed the liquid, decreased the amount of liquid accessed, and increased the amount of time required to empty a bottle (Ref. 19). A study analyzed poison center data to assess the association of adding flow restrictors to liquid acetaminophen products and subsequent rate of pediatric accidental unsupervised ingestions and

found that the rate of pediatric accidental unsupervised ingestions decreased after adding flow restrictors (Ref. 20).

On March 8, 2019, CPSC staff issued a letter to industry, “Nicotine Packaging Test Parameters,” providing the testing parameters that CPSC staff will use to assess compliance with the restricted flow requirement in 16 CFR 1700.15(d) (Ref. 21). 16 CFR 1700.15(d) requires “special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.” CPSC staff considered the PPPA’s flow restrictor provisions and recent draft American Society for Testing Materials International’s “Standard Test Method for Assessing Non-Metered Restricted Delivery Systems for Liquid Consumer Products.” The test methodology simulates a 5-year-old child gripping an inverted bottle for five seconds (Ref. 21). This method relies on mechanical testing to ensure flow restrictors are designed and manufactured to a consistent standard. The letter to industry further stated that manufacturers may use the provided test protocol or an equivalent testing method to determine compliance. On August 15, 2019, CPSC staff provided supplemental information on testing liquid nicotine packaging for rigid containers (Ref. 22).

FDA recognizes that to comply with the CNPPA requirements for restricted flow, manufacturers of liquid nicotine products may need to change certain aspects of their products. For liquid nicotine products that were on the market as of August 8, 2016, and that are then modified solely and only to the extent necessary to comply with the CNPPA requirements for restricted flow for liquid nicotine containers, FDA does not intend to initiate enforcement action against such modified products on the basis of these modifications.<sup>8</sup> For such products modified before the submission of a marketing application for the non-modified product, FDA recommends that manufacturers submit a single marketing application that describes both the product that was on the market as of August 8, 2016, and the modified product. For such products modified after the submission of a marketing application for the non-modified product, FDA recommends that manufacturers submit an amendment to the original application that describes the modifications implemented for CNPPA compliance.<sup>9</sup>

### III. REFERENCES

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<sup>8</sup> The compliance policy in this guidance provides that FDA does not intend to enforce violations of the premarket review requirements against such modified products solely on the basis of the modifications described in this guidance. FDA may take enforcement action against these products for violating the premarket review requirements for other reasons.

<sup>9</sup> This amendment should refer to the FDA-assigned submission tracking number (STN) provided to the applicant in the Acceptance letter of the original application for the product(s) of which these modifications apply.

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