4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-5324]

Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled "Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products." This guidance describes FDA's 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, specifically, modifications to battery-operated tobacco products solely to comply with UL 8139 and 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 guidance will enable tobacco manufacturers to upgrade their battery-operated tobacco products to UL 8139. It will also enable manufacturers to comply with the CNPPA requirements for flow restrictors for liquid nicotine containers. FDA is issuing this guidance to address battery safety concerns and youth exposure to liquid nicotine toxicity.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-5324 for "Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Nathan Mease or Lauren Belcher, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products." We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR

10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because the guidance presents a less burdensome policy that is consistent with public health. The guidance presents a less burdensome policy as it provides that FDA does not intend to enforce violations of the premarket review requirements against certain types of limited modifications to new tobacco products that were on the market as of August 8, 2016--specifically, modifications to battery-operated tobacco products solely to comply with UL 8139 and modifications to liquid nicotine products solely to comply with the CNPPA flow restrictor requirements for liquid nicotine containers. The guidance is consistent with public health because FDA believes that, in modifying their products to comply with UL 8139 or the CNPPA flow restrictor requirements, manufacturers will reduce the risk of battery-related adverse experiences and acute nicotine toxicity. Although this guidance document is for immediate implementation, it remains subject to comment in accordance with FDA's GGP regulation.

UL (formerly known as Underwriters Laboratories), along with the Consumer Product Safety Commission (CPSC), FDA, Health Canada, the American National Standards Institute (ANSI), and other 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), to help manufacturers address battery hazards for electronic cigarettes and other battery-operated tobacco products. The standard applies to 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. FDA recognizes that, to comply with UL 8139, manufacturers of battery-operated tobacco products may need to change certain aspects of their products.

On March 8, 2019 and August 15, 2019, CPSC staff issued letters to industry providing manufacturers with information regarding the testing parameters that CPSC will use to assess compliance with the restricted flow requirements of 16 CFR 1700.15(d). FDA has received inquiries about tobacco product manufacturers modifying their e-liquid products to comply with the restricted flow requirements. FDA recognizes that to comply with these requirements, manufacturers of liquid nicotine products may need to change certain aspects of their products.

In this guidance, FDA sets out its compliance policy for premarket review requirements with respect to 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 CNPPA flow restrictor requirements for liquid nicotine containers. This policy provides that FDA does not intend to enforce violations of the premarket review requirements against such modified products on the basis of these limited modifications.

The guidance represents the current thinking of FDA on these topics. 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in section 910(c)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387j(c)(1)(A)(i)) have been approved under OMB control number 0910-0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910-0673; and the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910-0684.

III. Electronic Access

Persons with access to the internet may obtain the document at either https://www.regulations.gov or https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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