directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* The Child Care and Development Fund (CCDF) Tribal Annual Report (ACF–700) requests Tribal Lead Agencies (TLAs) to provide annual Tribal aggregate information on services provided through the CCDF, which is required by CCDF regulations (45 FR parts 98 and 99). The revised ACF–700 report consists of an introductory section that provides program characteristics and two parts: (1) Administrative Data, and (2) Tribal Narrative. The content and format of the entire form have been revised to address Child Care and Development Block Grant (CCDBG) Act of 2014 changes and to reduce the reporting burden to TLAs.

Information from the ACF–700 will be included in the CCDF Report to Congress, as appropriate, and will be shared with TLAs to inform them of CCDF-funded activities.

*Respondents:* Tribal Governments.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Total number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|
| ACF–700 | 138 (Tribes with small allocation) | 3 | 19 | 7,866 | 2,622 |
| ACF–700 | 83 (Tribes with medium/large allocation). | 3 | 26 | 6,474 | 2,158 |

*Estimated Total Annual Burden Hours:* 4,780.

**Authority:** 42 U.S.C. 9857.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2019–25607 Filed 11–25–19; 8:45 am]

**BILLING CODE 4184–43–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 November 26, 2019.

**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.*

[FR Doc. 2019–25578 Filed 11–25–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–5465]**

### Center for Devices and Radiological Health Ethylene Oxide Sterilization Master File Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Ethylene Oxide Sterilization Master File Pilot Program (''EtO Pilot Program''). The EtO Pilot Program is voluntary and intends to allow companies (''sterilization providers'') that sterilize single-use medical devices using fixed chamber ethylene oxide (EtO) to submit a Master File when making certain changes between sterilization sites or when making certain changes to sterilization processes that utilize reduced EtO concentrations. Under this voluntary program, manufacturers (''PreMarket Application (PMA) holders'') of Class III devices subject to premarket approval that are affected by such changes may, upon FDA's permission, reference the Master File submitted by their sterilization provider in a postapproval report in lieu of submission of a premarket approval application (PMA) supplement. The EtO Pilot Program seeks to help ensure patient access to safe medical devices while encouraging new, innovative ways to sterilize medical devices that reduce the potential impact of EtO on the environment and on the public health while providing a regulatory approach that would address potential device shortages.

**DATES:** FDA is seeking participation in the voluntary EtO Pilot Program beginning November 26, 2019. See the ''Participation'' section for selection criteria for participation in the EtO Pilot Program and the ''Procedures'' section for instructions on how to submit a Master File for consideration for inclusion into the EtO Pilot Program. Up to nine eligible participants may be selected for the EtO Pilot Program.

**FOR FURTHER INFORMATION CONTACT:** Steven Elliott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4630, Silver Spring, MD 20993, 301–796–5285, *Steven.Elliott@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

EtO sterilization is an important sterilization method that is widely used to keep medical devices safe. Medical devices made from certain polymers (such as plastic or resin), metals, or glass—or devices that have multiple layers of packaging or hard-to-reach crevices (such as catheters)—are often sterilized with EtO to avoid product damage during the sterilization process. It is estimated that approximately 50 percent of all sterile medical devices in the United States are sterilized using EtO (Ref. 1).

For many medical devices, sterilization with EtO may be the only method [1] currently evaluated that effectively sterilizes and does not damage the device during the sterilization process. However, there have been recent concerns about the effects of EtO exposure and environmental emissions. Earlier this year, the FDA was made aware of the closures of two device sterilization facilities due to concerns about the level of EtO emissions (Ref. 2). Since then, the Agency has been closely monitoring the situation and working with device manufacturers affected by the closures to minimize impact to patients who need device access. FDA continues to work with manufacturers on site changes and engage with manufacturers about potential solutions to shortage concerns. FDA has also taken several actions to advance medical device sterilization, including sponsoring two innovation challenges to identify alternatives to EtO sterilization methods (Ref. 3) and approaches to reduce EtO emissions (Ref. 4), and convening the General Hospital and Personal Use Devices Panel on November 6 to 7, 2019 (November 2019 Panel Meeting), to discuss the role of EtO sterilization in maintaining public health (84 FR 46546; see also Ref. 5).

Before most sterile medical devices are on the market, FDA reviews premarket submissions to determine if the sterility information is adequate (*e.g.,* in accordance with internationally agreed upon voluntary consensus standards that the FDA recognizes). If a medical device manufacturer changes the method, process, or the facility identified in its original PMA submission for sterilizing its devices, the manufacturer generally needs to submit a PMA supplement so the Agency can review these changes (Ref. 6). However, considering recent events and concerns regarding EtO emissions, FDA recognizes the need to facilitate timely site changes to keep supply interruptions at a minimum and to facilitate changes to sterilization processes that utilize reduced EtO concentrations. At the November 2019 Panel Meeting, FDA received feedback from Panel members and stakeholders that the Agency could help prevent medical device shortages and advance medical device sterilization by expediting approvals of certain changes to EtO sterilization methods, processes, and facilities (Ref. 5).

For these reasons, FDA is announcing and soliciting participation in the EtO Pilot Program. Under this pilot program, sterilization providers that sterilize single-use medical devices using fixed chamber EtO would submit a Master File when making certain changes between sterilization sites or when making certain changes to sterilization processes that utilize reduced EtO concentrations. Under this voluntary program, PMA holders of Class III devices affected by such changes may, upon FDA's permission, reference the Master File submitted by their sterilization provider in a postapproval report, in accordance with § 814.84 (21 CFR 814.84), in lieu of submission of a PMA supplement, to satisfy the requirements of § 814.39(a) and (e) (21 CFR 814.39(a) and (e)). The pilot program is intended to provide expeditious review and feedback to sterilization providers and PMA holders on Master File submissions used to support changes made to sterilization site and/or processes in a postapproval report rather than a PMA supplement. FDA intends to evaluate pilot participation and the progress of the pilot in 6 months and provide any updates to the pilot in a subsequent notice, if appropriate. This postapproval report does not remove or replace the

[1] In this notice, ''method'' generally refers to the type of sterilization and ''processes'' generally refers to steps within that method to achieve a sterile device. Changes from a conventional EtO cycle to reduced/optimized EtO cycles would be considered a process change.