supportive services to seniors and their caregivers in an integrated system of long-term care. Information gathered through the Assessment and Evaluation of the Title VI Programs will inform ACL and its partners, other Federal agencies and administrators, current grantees, policymakers, and the field about ways to improve service delivery for elders and their caregivers and helping them to remain in their homes for as long as possible. For example, information gathered through the evaluation will be used to identify gaps and challenges in service delivery, as well as areas of further need.

Without this assessment and evaluation, Federal and local officials will not be able to determine whether the Title VI Programs are having the intended impact on AI/AN/NH elders and whether the grantees are meeting the individual goals of the programs. The new proposed data collection with further allow ACL to understand how successful the training and technical assistance provided to Title VI evaluation grantees was for their practice of data collection and use.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register 88 FR 56633** on August 18, 2023. There were no public comments received during the 60-day FRN.

Estimated Program Burden:

ESTIMATED PROGRAM BURDEN

Respondent type	Form name	Number of annual respondents	Number of responses per respondent	Average burden (in hours) per response	Annual burden hours
Program director	Program staff follow-up interview guide	12	1	1	12

Dated: October 30, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–24255 Filed 11–2–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4372]

Enforcement Policy for Clinical Electronic Thermometers; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled ''Enforcement Policy for Clinical Electronic Thermometers.'' This guidance applies to clinical electronic thermometers, which are regulated as class II devices. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on November 3, 2023.

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–2023–N–4372 for ''Enforcement Policy for Clinical Electronic Thermometers.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Enforcement Policy for Clinical Electronic Thermometers'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: David Wolloscheck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2416, Silver Spring, MD 20993–0002, 301–796–1480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Enforcement Policy for Clinical Electronic Thermometers.'' During the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE), FDA issued certain enforcement policies for non-invasive remote monitoring devices and clinical electronic thermometers. The policies regarding the modification of previously FDA-cleared clinical electronic thermometers within product code FLL were originally included in FDA's guidance ''Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' first issued in March 2020, and subsequently revised in June 2020, October 2020, and March 2023. The policies regarding the distribution and use of clinical electronic thermometers not previously cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) were outlined in FDA's guidance ''Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' issued in April 2020 and revised in March 2023.

At the time, FDA stated that the policies described in these guidances were intended to remain in effect only for the duration of the PHE related to COVID–19 declared by the Secretary of Health and Human Services in accordance with section 319 of the Public Health Service Act (42 U.S.C. 247d). On March 13, 2023, FDA announced in the **Federal Register** notice ''Guidance Documents Related to Coronavirus Disease 2019 (COVID–19)'' (88 FR 15417) that these guidance documents were being revised to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration, and that, during that time, FDA would further revise these guidances, among others. Consistent with what we said in the **Federal Register** notice of March 13, 2023, FDA has revised and consolidated the policies that apply to clinical electronic thermometers in this guidance. Elsewhere in this issue of the **Federal Register**, FDA is proposing to exempt certain clinical electronic thermometers—specifically clinical thermometers without telethermography or continuous temperature measurement functions—from premarket notification requirements under section 510(m) of the FD&C Act (see the **Federal Register** document ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments''). FDA intends to withdraw this guidance after any final exemption document has been published in the **Federal Register**.

The policies outlined in this guidance are organized by clinical thermometer type. The guidance describes enforcement policies that are intended to help foster compliance with certain applicable legal requirements for these devices.

The enforcement policies in this guidance apply to clinical electronic thermometers, which are regulated as class II devices under 21 CFR 880.2910, product code FLL. These devices include both contact and non-contact clinical electronic thermometers. This guidance supersedes ''Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency'' issued in April 2020 and updated in March 2023.

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this policy is being implemented immediately without prior comment, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)). FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on ''Enforcement Policy for Clinical Electronic Thermometers.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Enforcement Policy for Clinical Electronic Thermometers'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00020021 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Requirements; Unique Device Identification.	0910–0485
806	Medical Devices; Reports of Corrections and Removals	0910–0359
807, subparts A through D	Medical Device Registration and Listing	0910–0625
820	Current Good Manufacturing Practice, Quality Systems	0910–0073

Dated: October 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24291 Filed 11–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4372]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has identified certain class II clinical electronic thermometers that, when finalized, will be exempt from premarket notification requirements, subject to certain limitations. FDA is publishing this notice of that determination and requesting public comment in accordance with the procedures established by the 21st Century Cures Act. FDA will review any comments submitted within the 60-day comment period and will consider whether any modifications should be made to the exemption for certain clinical electronic thermometers prior to publication of its final determination in the **Federal Register**.

DATES: Either electronic or written comments on the notice must be submitted by January 2, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 2, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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.*
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- 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–2023–N–4372 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Center for Devices and Radiological Health, Food