Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4976]

Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' This draft guidance document, when finalized, will provide recommendations regarding non-clinical and clinical performance testing of certain pulse oximeters for medical purposes, including devices with a pulse oximeter function that estimates the amount of oxygen in arterial blood and pulse rate. These recommendations are being proposed based in part on concerns that the accuracy of pulse oximeters can be affected by, among other factors, a person's skin pigmentation. The recommendations are being proposed to inform the performance evaluation for these devices, to support premarket submissions, regardless of submission type, and to promote consistency and facilitate efficient review of these submissions. Among other topics, the draft guidance also proposes recommendations for labeling, which are intended to promote the safe and effective use of pulse oximeters and help users understand the benefits and risks associated with the use of the device. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–4976 for ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' 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 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 draft guidance document entitled ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Kumudhini Hendrix, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 1259, Silver Spring, MD 20993–0002, 240–402–5262.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document proposes recommendations regarding non-clinical and clinical performance testing of certain pulse oximeters for medical purposes, including devices with a pulse oximeter function that estimates the amount of oxygen in arterial blood and pulse rate. Pulse oximeters are widely used by many types of healthcare providers and lay-users to obtain an indirect measure of arterial blood oxygen saturation. These recommendations are being proposed based in part on concerns that the accuracy of pulse oximeters can be affected by, among other factors, a person's skin pigmentation. The recommendations are being proposed to inform the performance evaluation for these devices, to support premarket submissions, regardless of submission type, and to promote consistency and facilitate efficient review of these submissions. Among other topics, the draft guidance also proposes recommendations for labeling that are intended to promote the safe and effective use of pulse oximeters and help users understand the benefits and risks associated with the use of the device.

In recent years, FDA has engaged interested parties regarding how the Agency can help to ensure patients have access to high-quality, safe, and effective pulse oximeters intended for medical purposes. Current scientific evidence from laboratory desaturation studies suggests that there are accuracy differences in some pulse oximeters, especially in lower arterial blood oxygen saturations, between lightly and darkly pigmented individuals. On November 1, 2022, FDA convened the Anesthesiology and Respiratory Therapy Devices Panel (2022 Panel) of the Medical Devices Advisory Committee. The 2022 Panel indicated that clinical evidence for prescription pulse oximeters showed disparate performance in patients with dark skin pigmentation (as compared to patients with light skin pigmentation), which causes increased risk for the patient for their given disease outcome. The 2022 Panel also indicated that factors other than skin pigmentation, including but not limited to low perfusion, explain some of the disparate performance. The 2022 Panel recommended standardization of skin pigmentation assessment and that overall, pulse oximeters for clinical use should be more accurate. In a discussion paper issued on November 16, 2023, FDA requested public comment on a series of questions related to an approach to improve the quality of premarket studies and associated methods used to evaluate the performance of pulse oximeters (Docket No. FDA–2023–N–4976), taking into consideration a participant's skin pigmentation and participant-reported race and ethnicity. On February 2, 2024, FDA reconvened the Panel (''2024 Panel'') to discuss a proposed approach for these issues. The 2024 Panel was also asked to discuss the type and amount of data that should be provided by manufacturers to FDA to evaluate the performance of pulse oximeters submitted for premarket review, including prescription and over-the-counter indications, and labeling considerations. After discussing the advantages and challenges, the 2024 Panel was in general agreement with the proposed approach. FDA considered comments from the discussion paper and Panel meetings and incorporated the feedback as appropriate in developing this draft guidance. FDA strongly encourages interested persons to submit comments regarding this topic, including any clinical studies or information that may be relevant for consideration.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.'' 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 draft 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* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Pulse Oximeters for Medical Purposes—Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001605 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 or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption.	0910–0078
860, subpart D	De Novo classification process.	0910–0844
''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 Regulations; Unique Device Identification.	0910–0485

21 CFR part or guidance	Topic	OMB control No.
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: December 26, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0053]

Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act; 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 or Agency) is announcing the availability of a final guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' This guidance updates the previous version of the guidance, of the same title, issued on November 17, 2023, and finalizes the concurrently issued draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' This guidance finalizes a list of device product codes for which a manufacturer of such devices is required to notify FDA in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (hereafter referred to as the ''506J Device List'') and clarifies that manufacturers may submit voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a public health emergency (PHE).

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

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

Electronic Submissions

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- *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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Instructions: All submissions received must include the Docket No. FDA–2022–D–0053 for ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.'' 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.

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