DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers; Guidance for Industry; Availability; Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request

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 for industry entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to health care providers (HCPs) engaged in prescribing or administering medical products to individual patients. This guidance finalizes the revised draft guidance of the same title issued in October 2023. The October 2023 revised draft guidance revised and replaced the draft guidance entitled ''Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices,'' issued in March 2014, which itself revised the final guidance entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,'' issued in January 2009. This guidance is not for current implementation, pending the Office of Management and Budget's (OMB's) decision on the collection of information.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025. Submit written comments on the collection of information by February 21, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find the particular information collections by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control numbers that FDA is seeking to revise are 0910–0686 and 0910–0485. Also include the FDA docket number found in brackets in the heading of this document. 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–2008–D–0053 for ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; 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; or the Policy and Regulations Staff, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kathleen David, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Room 3203, Silver Spring, MD 20993–0002, 301–796–1200; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Stephanie Philbin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–837–7151; Kathryn Dennehy, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–7002; or Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

Regarding the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to HCPs engaged in prescribing or administering medical products to individual patients. FDA is issuing this guidance to provide reassurance to firms that, if they choose to provide communications consistent with the recommendations in this guidance, FDA does not intend to use the firm's dissemination of such communication standing alone as evidence of a new intended use. Additionally, FDA does not expect a firm to submit such a communication to the Agency at the time the communication is initially shared with HCPs. We acknowledge that firms communicate in other ways and with other audiences, and this guidance neither speaks to nor intends to convey any views on communications that are not within the scope of the enforcement policy outlined in this guidance.

The fact that a communication by a firm does not share all the characteristics of communications that are within the scope of this enforcement policy does not alone mean that FDA intends to rely on it to establish a new intended use. A key tenet underlying this enforcement approach is that, to promote the public health, any individual firm-initiated communication of scientific information about unapproved use(s) of that firm's approved/cleared medical product(s) should be truthful and non-misleading, and provide and appropriately present all information necessary for HCPs to understand and evaluate the strengths and weaknesses, validity, and clinical utility of the scientific information on unapproved use(s) in that specific communication. Accordingly, the guidance provides recommendations consistent with those principles. The guidance also describes the characteristics of the specific source publications contained in firm-initiated communications that fall within the enforcement policy outlined in this guidance.

Specifically, this guidance provides recommendations for firms initiating the sharing with HCPs of:

- Source publications that are:

—Published scientific or medical journal articles (reprints)

—Published clinical reference resources, as follows:

  - Clinical practice guidelines (CPGs)
  - Scientific or medical reference texts (reference texts)
  - Materials from digital clinical practice resources

- Firm-generated presentations of scientific information on unapproved use(s) provided with a source publication

For the purposes of this guidance, these specific types of firm-initiated communications to HCPs, in combination with the disclosures recommended in this guidance, are referred to as scientific information on unapproved use(s) of approved/cleared medical product communications (hereafter referred to as ''SIUU communications'').

This guidance finalizes the revised draft guidance of the same title issued in October 2023 (88 FR 73031). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include (1) reorganizing the guidance to include dedicated glossary and policy sections; (2) revising the recommendations for source publications to provide additional specificity and examples to illustrate the recommendations; (3) refining language around presentational considerations to provide additional clarity and an additional example; and (4) updating the section on firm-generated presentations to specify that the recommendations apply to firm-generated presentations of scientific information from any of the source publications addressed in the guidance. In addition, editorial changes were made for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers.'' 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

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information for OMB review and clearance. This guidance is not for current implementation, pending OMB's decision on the collection of information.

Manufacturer Communications on Approved and Unapproved Uses of Drugs OMB Control Number 0910–0686—Revision; and Medical Device Labeling

OMB Control No. 0910–0485—Revision

The guidance document entitled ''Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers'' discusses third-party disclosure recommendations regarding information that we recommend firms include in SIUU

communications if the firms choose to publicly share such communications.

In the **Federal Register** of October 24, 2023 (88 FR 73031), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the four information collection topics solicited in the notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—OMB CONTROL NO. 0910–0686 [1]

Information collection activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established; section V. Q2.	747	30	22,410	0.1 (6 minutes)	2,241
A statement disclosing the FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling; section V. Q2.	747	27	20,169	0.1 (6 minutes)	2,016.9
A statement disclosing any limitations, restrictions, cautions, warnings, or precautions described in the FDA-required labeling about the unapproved use(s); section V. Q2.	747	5	3,735	0.2 (12 minutes) ...	747
A copy of the most current FDA-required labeling (or a mechanism for obtaining this labeling, as appropriate); section V. Q2.	747	27	20,169	0.1 (6 minutes)	2,016.9
A statement describing any contraindication(s) in the FDA-required labeling for the medical product; section V. Q2.	747	3	2,241	0.1 (6 minutes)	224.1
A statement describing any serious, life-threatening, or fatal risks posed by the medical product that are in the FDA-required labeling for the medical product or known by the firm and that are relevant to the unapproved use(s). If a risk evaluation and mitigation strategy (REMS) has been established under 21 U.S.C. 355–1, the statement should disclose that fact and should describe the goal(s) of the REMS; section V. Q2.	747	25	18,675	0.2 (12 minutes) ...	3,735
A statement identifying any authors, editors, or other contributors to publication(s) included in the SIUU communication who were employees of or consultants to or who received compensation from the firm at the time of writing, editing, or contributing to the publication, to the extent a firm acting reasonably would know of such relationship; section V. Q2.	747	20	14,940	0.2 (12 minutes) ...	2,988
In the case of an SIUU communication that includes one or more source publications primarily focused on a particular scientific study or studies, for each such study where the following information is not included in the source publication, provide a description of:. —All material aspects of study design, methodology, and results; —All material limitations related to the study design, methodology, and results; —Any conclusions—from other scientifically sound studies that evaluated the same or similar hypotheses or research questions—that are in conflict with the conclusions from the studies or analyses described in the source publication(s). The citations for any such studies should also be included; section V. Q2.	747	20	14,940	2.75	41,085
The publication date of any referenced or included source publication (if not specified in the source publication or citation); section V. Q2.	747	3	2,241	0.1 (6 minutes)	224.1
When a firm shares an SIUU communication that does not include a firm-generated presentation, but does include an unabridged CPG or reference text in its entirety that discusses a wide range of medical products and that discussion is not primarily focused on one or more of a firm's medical products, the firm should include, in lieu of some of the specific disclosures listed above, a more general statement in the SIUU communication, such as ''This [CPG/reference text] describes some uses of medical products that are not approved by FDA, and the safety and effectiveness of any unapproved use(s) have not been established.''; section V. Q4.	747	3	2,241	0.1 (6 minutes)	224.1
When a firm shares an SIUU communication that includes a firm-generated presentation of scientific information on unapproved use(s) provided with a source publication, that SIUU communication should clearly disclose what portions of the SIUU communication are firm-generated; section V. Q5.	747	10	7,470	0.1 (6 minutes)	747
Total	.....	.....	129,231	.....	56,249.1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a current listing of firms promoting human and animal drug products in calendar year (CY) 2022, we assume 747 firms (''number of respondents'' in table 1) may each choose to publicly share 30 SIUU communications annually. Our estimate of the burden per disclosure (2.5 hours) reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—OMB CONTROL NO. 0910–0485 [1]

Information collection activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
A statement that the unapproved use(s) of the medical product has not been approved by FDA and that the safety and effectiveness of the medical product for the unapproved use(s) has not been established; section V. Q2.	261	30	7,830	0.1 (6 minutes)	783
A statement disclosing the FDA-approved use(s) of the medical product, including any limitations of use specified in the FDA-required labeling; section V. Q2.	261	27	7,047	0.1 (6 minutes)	704.7
A statement disclosing any limitations, restrictions, cautions, warnings, or precautions described in the FDA-required labeling about the unapproved use(s); section V. Q2.	261	5	1,305	0.2 (12 minutes) ...	261
A copy of the most current FDA-required labeling (or a mechanism for obtaining this labeling, as appropriate); section V. Q2.	261	27	7,047	0.1 (6 minutes)	704.7
A statement describing any contraindication(s) in the FDA-required labeling for the medical product; section V. Q2.	261	3	783	0.1 (6 minutes)	78.3
A statement describing any serious, life-threatening, or fatal risks posed by the medical product that are in the FDA-required labeling for the medical product or known by the firm and that are relevant to the unapproved use(s). If a risk evaluation and mitigation strategy (REMS) has been established under 21 U.S.C. 355–1, the statement should disclose that fact and should describe the goal(s) of the REMS; section V. Q2.	261	25	6,525	0.2 (12 minutes) ...	1,305
A statement identifying any authors, editors, or other contributors to publication(s) included in the SIUU communication who were employees of or consultants to or who received compensation from the firm at the time of writing, editing, or contributing to the publication, to the extent a firm acting reasonably would know of such relationship; section V. Q2.	261	20	5,220	0.2 (12 minutes) ...	1,044
In the case of an SIUU communication that includes one or more source publications primarily focused on a particular scientific study or studies, for each such study where the following information is not included in the source publication, provide a description of:. —All material aspects of study design, methodology, and results —All material limitations related to the study design, methodology, and results —Any conclusions—from other scientifically sound studies that evaluated the same or similar hypotheses or research questions—that are in conflict with the conclusions from the studies or analyses described in the source publication(s). The citations for any such studies should also be included; section V. Q2	261	20	5,220	2.75	14,355
The publication date of any referenced or included source publication (if not specified in the source publication or citation); section V. Q2.	261	3	783	0.1 (6 minutes)	78.3
When a firm shares an SIUU communication that does not include a firm-generated presentation, but does include an unabridged CPG or reference text in its entirety that discusses a wide range of medical products and that discussion is not primarily focused on one or more of a firm's medical products, the firm should include, in lieu of some of the specific disclosures listed above, a more general statement in the SIUU communication, such as ''This [CPG/reference text] describes some uses of medical products that are not approved by FDA and the safety and effectiveness of any unapproved use(s) have not been established.''; section V. Q4.	261	3	783	0.1 (6 minutes)	78.3
When a firm shares an SIUU communication that includes a firm-generated presentation of scientific information on unapproved use(s) provided with a source publication, that SIUU communication should clearly disclose what portions of the SIUU communication are firm-generated; section V. Q5.	261	10	2,610	0.1 (6 minutes)	261
Total	.....	.....	45,153	.....	19,653.3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on an estimated number of device firms marketing products in calendar year (CY) 2022, we assume 261 firms (''number of respondents'' in table 1) may each choose to publicly share 30 SIUU communications annually. Our estimate of the burden per disclosure (2.5 hours) reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

FDA is issuing this final guidance subject to OMB approval of the collection of information. Before implementing the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collection of information.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31539 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

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