DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0205 (Formerly 2007D–0252)]

Pulse Oximeters—Premarket Notification Submissions [510(k)s]; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Pulse Oximeters—Premarket Notification Submissions [510(k)s].'' This guidance document pertains to non-invasive pulse oximeters intended for prescription use to measure arterial blood oxygen saturation (SpO_2) and pulse rate. This document supersedes the General Guidance Document entitled ''Device: Non-Invasive Pulse Oximeter'' issued on September 7, 1992, and represents the Agency's current thinking in regards to information that should be included in a premarket submission for a non-invasive pulse oximeter.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Pulse Oximeters—Premarket Notification Submissions [510(k)s]'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2532, Silver Spring, MD 20993–0002, 301–796–6274.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed this guidance document to assist industry in preparing a Premarket Notification (510(k)) for a pulse oximeter. The device is intended for non-invasive measurement of SpO_2 and pulse rate. In the **Federal Register** of July 19, 2007 (72 FR 39631), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 17, 2007. Two sets of comments were received with recommendations related to organization, terminology, references to standards, labeling, test recommendations, and data analysis. In response, FDA revised the guidance document to address the comments and clarify our recommendations as appropriate. This document supersedes the guidance document ''Non-Invasive Pulse Oximeter General Guidance Document,'' dated September 7, 1992.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on non-invasive pulse oximeters intended for prescription use to measure SpO_2 and pulse rate. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Pulse Oximeters—Premarket Notification Submissions [510(k)s],'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1605 to identify the guidance you are requesting.

IV. 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. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: February 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04870 Filed 3–1–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Non-HIV Diagnostics, Food Safety, Sterilization/Disinfection and Bioremediation.