II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents.'' 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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1557 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: July 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13952 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0252]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Pulse Oximeters—Premarket Notification Submissions [510(k)s].'' The draft guidance describes FDA's recommendations about the content of premarket notification submissions (510(k)s) for pulse oximeter devices.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 17, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Pulse Oximeters—Premarket Notification Submissions [510(k)s]'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: Neel J. Patel, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

SUPPLEMENTARY INFORMATION:

I. Background

A pulse oximeter is a device intended for the non-invasive measurement of arterial blood oxygen saturation and pulse rate. It is a class II device in accordance with 21 CFR 870.2700. The draft guidance describes FDA's recommendations about the accuracy, performance, biocompatibility, safety, and labeling of pulse oximeters. In particular, the draft guidance incorporates the recommendations of the Anesthesiology and Respiratory Therapy Devices Panel (the Panel). At the open public meeting held on May 13, 2005, the Panel made recommendations regarding general issues for pulse oximeters, including reflectance sensor technology and the clinical validation of accuracy when the device is intended for neonatal use. FDA agreed and incorporated these recommendations into the draft guidance. (Transcripts of the May 13, 2005, meeting are available at *http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005–4141T1.htm*.)

II. Significance of Guidance

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 agency's current thinking on ''Pulse Oximeters—Premarket Notification Submissions [510(k)s].'' 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 draft guidance may do so by using the Internet. To receive ''Pulse Oximeters—Premarket Notification Submissions [510(k)s],'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1605) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

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V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Received comments are to be identified 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.

Dated: July 3, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–14012 Filed 7–18–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Mice Genetically Deficient in the Chemoattractant Receptor FPR (Formyl Peptide Receptor)

Description of Invention: The present research tool is a knockout mouse model ($FPR^{-/-}$) that lacks the high affinity N-formylpeptide receptor (FPR), created by targeted gene disruption.

N-formylpeptides derive from bacterial and mitochondrial proteins, and bind to specific receptors on mammalian phagocytes. Since binding induces chemotaxis and activation of phagocytes in vitro, it has been postulated that N-formylpeptide receptor signaling in vivo may be important in antibacterial host defense, although direct proof has been lacking. The inventors have found that $FPR^{-/-}$ mice have no obvious developmental defects and do not develop spontaneous infection when derived in specific pathogen-free conditions. This suggests that, under these conditions, FPR is dispensable. However, when challenged with L. monocytogenes, FPR-deficient mice have accelerated mortality and increased bacterial burden in liver and spleen early after infection, which suggests a role for FPR in host defense, specifically through regulation of innate immunity.

Applications and Modality: New mouse model to study antibacterial host defense.

Market: Research tool useful for innate immunity studies.

Development Status: The technology is a research tool.

Inventors: Philip Murphy and Ji-Liang Gao (NIAID).

Patent Status: HHS Reference No. E–258–2007/0—Research Tool.

Publication: JL Gao, EJ Lee, PM Murphy. Impaired antibacterial host defense in mice lacking the N-formylpeptide receptor. J Exp Med. 1999 Feb 15;189(4):657–662.

Licensing Status: This technology is not patented. The mouse model will be transferred through a Biological Materials License.

Licensing Contact: Peter J. Soukas, J.D.; 301/435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The Laboratory of Molecular Immunology, NIAID, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize FPR knockout mice. Please contact Philip Murphy, M.D. at Tel: 301–496–8616 and/or *pmm@nih.gov* for more information.

Steroid Derivatives as Inhibitors of Human Tyrosyl-DNA Phosphodiesterase (Tdp1)

Description of Technology: Tyrosyl-DNA phosphodiesterase (Tdp1) is an enzyme that repairs topoisomerase I (Top1)-mediated DNA damage induced by chemotherapeutic agents and ubiquitous DNA lesions that interfere with transcription. The current technology are steroid derivatives that human inhibit Tdp1.

Currently, there are various types of Top1 inhibitors used in chemotherapy, e.g., camptothecin. However, Tdp1 inhibitors are expected to be effective in combination therapy with Top1 inhibitors for the treatment of cancers. Combining Tdp1 inhibitors with Top1 inhibitors would allow Tdp1 to potentiate the antiproliferative activity of Top1 inhibitors. In addition to Tdp1's effect on Top1, Tdp1 inhibitors can also exhibit antitumor activity independently, as tumors are shown to