the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also discuss and make recommendations regarding general issues for pulse oximeters. The issues include the equivalence of reflectance sensor technology to transmissive sensor technology; validation recommendations for neonatal intended use; and over-the-counter (OTC) use of pulse oximeters.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by May 3, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 240–276–0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 13, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7948 Filed 4–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0410]

Guidance for Industry and Food and Drug Administration Staff on Application User Fees for Combination Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled ''Application User Fees for Combination Products.'' This document provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance also describes how the ''barrier to innovation'' waiver provision under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the act) may be applied to innovative combination products in the infrequent situation where FDA requires the submission of two marketing applications.

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

ADDRESSES: Submit written requests for copies of this guidance to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, Rockville, MD 20855, or FAX: 301–427–1935. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments concerning this 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Application User Fees for Combination Products.'' In the **Federal Register** of September 28, 2004 (69 FR 57942), FDA issued a notice of availability of a draft guidance document covering the same topic.

As defined under 21 CFR 3.2(e), a combination product is a product comprised of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product. Depending upon the type of combination product, approval, clearance, or licensure may be obtained through submission of a single marketing application, or through separate marketing applications for the individual constituent parts of the combination product. For most combination products, a single marketing application is sufficient for the product's approval, clearance, or licensure. In some cases, two marketing applications may be submitted for a combination product when one application would suffice. For example, a sponsor may choose to submit two applications when one would suffice in order to receive some benefit from having two applications. In other cases, FDA may determine that two marketing applications are necessary.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA). PDUFA authorized FDA to collect fees from companies that produce certain human drug and biological products. The Medical Device User Fee and Modernization Act of 2002 amended the act to provide for user fees for the review of device applications. When a company requests approval of a new drug, device, or biological product prior to marketing, it must submit an application along with a fee to support the review process.

This document provides guidance to industry and FDA staff on marketing application user fees for combination products. The guidance document explains that combination products for which a single marketing application is submitted, should be assessed the user fee associated with that particular type of marketing application. The document explains that if a sponsor chooses to submit two marketing applications when one would suffice, a user fee for each application would ordinarily be assessed. The document also explains that in the infrequent situation where FDA requires two marketing applications for a combination product, two application fees would ordinarily be assessed. However, the guidance also describes how the PDUFA ''barrier to innovation'' waiver provision may be applied to innovative combination products for which FDA requires the submission of two marketing applications. Such a waiver would provide a reduction in application user

fees equivalent to the additional fee burden associated with the submission of two marketing applications. This guidance does not address how FDA should determine whether a single or multiple marketing applications should be submitted for a combination product. Such guidance is in development and will be provided separately for public review and comment.

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 application user fees for combination products. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/oc/combination* or by e-mailing the Office of Combination Products at *combination@fda.gov*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 15, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7947 Filed 4–20–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0041]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Content of Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' This guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. FDA's regulations require that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. The guidance provides information on submitting the content of labeling in electronic format for review with new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs) for biological products that meet the definition of drug in the Federal Food, Drug, and Cosmetic Act.

DATES: Submit written or electronic comments on agency guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800.

Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–594–5411, e-mail: *levinr@cder.fda.gov*, or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling regulation), which requires the submission of the content of labeling in electronic format for marketing applications. The requirements of the electronic labeling rule can be found in § 314.50(l) (21 CFR 314.50(l)) for NDAs, § 314.94(d) for ANDAs, § 601.14(b) for BLAs, and § 314.81(b) for annual reports on marketing applications. The regulations specify that the content of labeling must be submitted electronically in a form that FDA can process, review, and archive. The regulations also state that FDA will periodically issue guidance on how to provide the electronic submission.

II. The Guidance

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' The guidance provides information on how to submit the content of labeling in electronic format.

In the preambles of the proposed and final rules on electronic labeling, FDA identified portable document format (PDF) as the only type of electronic file format that the agency has the ability to accept for processing, reviewing, and archiving. Recent recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics and mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) have created a new role for electronic labeling information. Electronically formatted content of labeling will be used to support Federal health information management initiatives such as electronic prescribing; the electronic health record (EHR), which will provide health care providers, patients, and other authorized users access to patient information in electronic format; and