Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On February 9, 2007, West-ward Pharmaceutical Corp. (West-ward), on behalf of Hikma Farmaceutica (Portugal), S.A., submitted a citizen petition (Docket No. 2007P–0052/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether Brethine (terbutaline sulfate) injection (NDA 18–571), manufactured by AaiPharma, was withdrawn from sale for reasons of safety or effectiveness. AaiPharma ceased manufacture of Brethine injection and it was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book in August of 2006.

Brethine injection was first approved in 1981; this approval was for a glass ampoule container closure system. In 2004 AaiPharma received approval of a glass vial container closure system for a Brethine injection formulation that contained 0.055 percent disodium edetate. When Brethine injection was discontinued, an approved generic was chosen as the replacement reference listed drug. The replacement reference listed drug does not contain 0.055 disodium edetate and is based on the original glass ampoule formulation. Therefore, West-ward requests that the agency make a determination that the reformulated version of Brethine injection was not withdrawn for safety or efficacy reasons.

FDA has reviewed its records and, under § 314.161, has determined that Brethine (terbutaline sulfate) injection was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Brethine containing 0.055 disodium edetate was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Furthermore we have determined that the change in formulation was not for safety or efficacy reasons. Our files indicate that disodium edetate was added as a protectant against certain oxidation-derived terbutaline impurities and degradants when the manufacturing site and container closure system were changed. Accordingly, the agency will continue to list terbutaline sulfate injection in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to terbutaline sulfate injection may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 12, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–13950 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–0201]**

### Draft Guidance for Industry and Food and Drug Administration Staff; Premarket Notification Submissions for Medical Devices That Include Antimicrobial Agents; 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 ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents.'' This draft guidance is intended to assist device manufacturers interested in preparing premarket notification (510(k)) submissions for their medical devices that include antimicrobial agents. This guidance recommends testing and labeling for 510(k) submissions for devices that include antimicrobial agents. It is intended as a supplement to other device-specific guidance issued by the Center for Devices and Radiological Health (CDRH).

**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 comments 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 ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents'' 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:** Michelle Rios, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3747.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In recent years there has been increased interest in adding antimicrobial agents to medical devices for specific or limited indications for use, such as reduction or prevention of a device-related infection, or reduction or inhibition of colonization of a medical device. FDA developed this draft guidance to assist device manufacturers in preparing premarket notification (510(k)) submissions for medical devices that include antimicrobial agents.

**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.