determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

In a citizen petition dated July 11, 2006 (Docket No. 2006P–0281/CP1), submitted under 21 CFR 10.30, Camargo Pharmaceutical Services, LLC, requested that the agency determine whether ORUDIS KT (ketoprofen) tablets, 12.5 mg, were withdrawn from sale for reasons of safety or effectiveness. ORUDIS KT (ketoprofen) tablets, 12.5 mg, are the subject of approved NDA 20–429 held by Wyeth Consumer Healthcare (Wyeth). ORUDIS KT, an over-the-counter nonsteroidal anti-inflammatory (NSAID) drug indicated for the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, minor pain of arthritis and menstrual cramps. ORUDIS KT (ketoprofen) is also indicated to temporarily reduce fever. In a letter dated August 24, 2005, Wyeth informed FDA of the firm's decision to discontinue manufacture of ORUDIS KT (ketoprofen) tablets, 12.5 mg, and the product was moved to the ''Discontinued Drug Product List'' section of the Orange Book.

The agency has determined that ORUDIS KT (ketoprofen) tablets, 12.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner referenced, among other information, certain labeling changes intended to assist consumers in the safe use of the drug, and some adverse event reports. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this notice, ORUDIS KT (ketoprofen) tablets, 12.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ORUDIS KT (ketoprofen) tablets, 12.5 mg, 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 ORUDIS KT (ketoprofen) tablets, 12.5 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. 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: August 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15843 Filed 8–13–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 16 and 17, 2007, from 8 a.m. to 5 p.m.

Location: The National Labor College, Lane Kirkland Center, Solidarity Hall, 10000 New Hampshire Ave., Silver Spring, MD. The telephone number is 301–431–6400.

Contact Person: Cathy A. Miller, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *Cathy.Miller1@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 16, 2007, the committee will discuss regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations on this topic from Shire Development, Genzyme Corp, and Fresenius Medical Care.

On October 17, 2007, the committee will discuss data requirements and study designs appropriate to characterize the durability of treatment effect of REVATIO (sildenafil citrate) Pfizer, Inc., in pulmonary arterial hypertension in children.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

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 on or before October 1, 2007. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on both days for the corresponding agenda. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 21, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 24, 2007.

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 Cathy Miller at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: August 7, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15834 Filed 8–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0307] (Formerly Docket No. 98D–0307)

Guidance for Industry on Exports Under the Food and Drug Administration Export Reform and Enhancement Act of 1996; 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 ''FDA Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996.'' The guidance document addresses issues pertaining to the exportation of human drugs, animal drugs, biologics, devices, food, food additives, color additives and dietary supplements under the FDA Export Reform and Enhancement Act.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Barbara Ward-Groves, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480 or 404–253–1221.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 12, 1998 (63 FR 32219), FDA published a draft guidance document entitled ''FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.'' FDA wrote the draft guidance to help interested parties understand and comply with the FDA Export Reform and Enhancement Act. Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Public Law 104–134, as amended by Public Law 104–180) significantly changed the export requirements for human drugs, animal drugs, biologics, devices, and, to a limited extent, food additives. For example, before the law was enacted, most exports of unapproved new drug products could only be made to 21 countries identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to various restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA). (Currently, the EU countries are Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Currently, the EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.)

The guidance document provides information on the statutory and regulatory requirements for exporting FDA-regulated products, including general requirements for products exported under section 801 of the act, labeling requirements for drugs and biologics exported under section 801(e) of the act, export requirements for unapproved drugs, biologics, and devices under section 802(b) of the act, exports of unapproved drugs and devices for investigational use, exports of unapproved drugs and devices in anticipation of foreign approval, exports of drugs and devices for diagnosing, preventing, or treating a tropical disease or disease ''not of significant prevalence in the United States,'' and export notifications to FDA. The guidance document announced in this notice finalizes the draft guidance issued June 12, 1998.

The guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115) and represents FDA's current thinking on exports under sections 801(e) and 802 of the act. 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 statutes and regulations.

II. 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. 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.

III. Electronic Access

An electronic version of the guidance is available on the Internet at *http://www.fda.gov* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 7, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–15840 Filed 8–13–07; 8:45 am]

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