DATES: Submit written or electronic comments on this notice by October 15, 2007.

ADDRESSES: Submit written comments on this notice 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: Terrie L. Crescenzi, Office of the Commissioner (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7864.

SUPPLEMENTARY INFORMATION: Because of the positive response to the agency's guidance on rheumatoid arthritis, the agency has recognized the need for more information on the development of human drugs, biological products, and medical devices for the treatment and prevention of OA. FDA is requesting assistance from the public in conducting scientific analyses for the purpose of finalizing the agency's current draft OA guidance.

Specifically, the agency is inviting any interested group or consortium of interested groups from academia, industry, practitioners, and patients and their representatives to conduct and manage the coordination of a critical appraisal of certain fundamentals of the science related to OA. Initially, the party or parties would organize and hold a public meeting to discuss relevant questions related to OA assessment and trial design (a number of which are suggested in this notice). FDA believes a public meeting will lead to conceptual advances not now present, and the expression of such advances in a series of concept papers. These concept papers would then be discussed at subsequent workshops, soliciting feedback from all parties including regulators from the United States and elsewhere. Such discussion would emphasize the rationale for various approaches to key issues.

FDA welcomes other suggestions of activities that could be undertaken as part of this guidance development effort. To provide a starting point for discussion, FDA has developed a list of some key concepts that the interested parties may want to consider for discussion at the meeting.

1. Should the *scope* of the guidance apply to OA alone? Are there particular clinical subgroups of OA that need to be explicitly considered and addressed?

2. For a *claim of symptomatic relief* in OA, what are the optimal outcome measures and trial designs? Currently, withdrawal and flare designs are commonly used. These designs, while believed to be predictive, may lack generalizability. It is also difficult to understand the actual size of the treatment effect based on a flare design. If withdrawal and flare designs are not optimal, what alternative designs could be used to support a symptomatic relief claim? What should the size and duration of exposure of the safety database be for symptomatic relief?

3. Is a *claim of decreased rate of progression* useful and, if so, what would be the appropriate outcome measure(s) to establish the claim? What is the desirable duration of a trial for this claim? What comparator arms might be used?

4. For a *claim of prevention or risk reduction* for the development of OA, what are potential outcome measures? If biomarkers are used, what is their state of qualification? What is the desirable duration of a trial for such a claim? What is an appropriate safety database for a prevention of OA claim?

5. Are there *additional claims* that should be considered? If so, what outcome measures and trial designs should be used?

6. In any *long term studies*, what are the best statistical comparisons for inference testing (is, for instance, a comparison of mean changes from baseline suitable or should responses be graded according to points on established scales)? Because longer trials inevitably have substantial dropouts, what imputation methods for dropouts are most appropriate or should the trial results be based on a survival analysis or a time to event (for treatment failure) analysis?

Interested persons should submit comments and expressions of interest in conducting and managing a critical appraisal to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, 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. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15844 Filed 8–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0281]

Determination That ORUDIS KT (Ketoprofen) Tablets, 12.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ORUDIS KT (ketoprofen) tablets, 12.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ketoprofen tablets, 12.5 mg.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic 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 generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn 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).

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]

BILLING CODE 4160–01–S

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.