agencies, and international organizations to strengthen capacity of countries around the world to improve public health. To carry out its mission, the division performs the following functions: (1) Works with partners to build strong, transparent, and sustained public health systems through training, consultation, capacity building, and technical assistance in applied epidemiology, public health surveillance, evaluation, and laboratory systems; and promotes organizational excellence in public health through strengthening leadership and management capacity; (2) assists in developing and implementing COGH policy on public health system strengthening and sustainability; and (3) collaborates with other ODC organizations, Federal agencies, international agencies, partner countries, and non-governmental organizations assisting ministries of health to build public health capacity in other areas of public health.

Office of the Director (CWF1). (1) Provides leadership, overall direction, and evaluation for the division; (2) formulates and implements CDC's strategy for developing global public health capacity in applied epidemiology, public health systems, laboratory operations and management, and leadership; (3) provides leadership and guidance on policy, program planning, program management, and operations; (4) plans, allocates, and monitors resources; (5) provides leadership in assisting national ministries of health, international agencies, and non-governmental organizations in the delivery of epidemiologic services and the development of international epidemiologic networks; (6) provides liaison with other CDC organizations, other Federal agencies, national ministries of health, and international organizations; and (7) provides consultations with partners and stakeholders including nongovernmental organizations and the private sector on program development and overall public health systems and sub-systems.

Sustainable Management Development Program (CWF12). (1) Partners with ministries of health, educational institutions, and non-governmental organizations in developing countries, to promote organizational excellence in public health through strengthening leadership and management capacity; (2) works with partners to build capacity for public health leadership and management development through a multi-phased approach including situational analysis, capacity development, technical assistance, and sustainability; (3) develops strategic institutional partnerships for public health leadership and management capacity-building efforts; (4) develops faculty to enhance in-country leadership and management training capacity through the Management for International Public Health course and in-country training-of-trainers; (5) provides support to training faculty in partner institutions to conduct performance needs assessments; develops locally appropriate curricula; and designs in-country leadership and management workshops that provide participants with practical skills needed to manage public health teams, programs, and organizations; and (6) works with partner institutions to ensure the long-term sustainability of global public health leadership and management development programs.

Capacity Development Branch (CWFB). (1) With partners, designs and conducts evidence-based instruction in public health disciplines needed to strengthen their public health systems, including instructional design, epidemiology, surveillance, laboratory operations and management, communications, and economic evaluation; (2) working with the technical program components, provides consultation to ministries of health in development of surveillance systems (e.g. Integrated Disease Surveillance, injury, chronic diseases, infectious diseases, etc.); (3) creates and maintains computer-based and distance-based learning methods, and develops the capacity of partners to create, evaluate, and share their own; (4) develops and evaluates competency-based training materials; (5) maintains a divisional training material library and Web site; and (6) collaborates within CDC and with national or international organizations in development of competency-based training materials, evaluation of training, and design of surveillance systems needed to accomplish the mission.

Program Development Branch (CWFC). (1) Assists partners in assessing their needs for health systems strengthening; (2) plans, directs, supports, and coordinates field epidemiology and laboratory training programs, Data for Decision Making Projects, and other partnerships with ministries of health; (3) provides leadership and management oversight in assisting ministries of health in capacity building by training epidemiologists and other health professionals through the development of competency-based, residency-style, applied training programs; (4) provides leadership and expertise in assisting national ministries of health to utilize trained public health workers for developing health policy, and implementing and evaluating health programs; (5) assigns and manages expert consultants as long-term, in-country advisors to ministry of health programs; and (6) collaborates within CDC, with other Federal agencies, and with national and international organizations in support of partner programs.

Dated: August 3, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 07–3953 Filed 8–13–07; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0077 (formerly 98D–0077)]

Clinical Development Programs for Human Drugs, Biological Products, and Medical Devices for the Treatment and Prevention of Osteoarthritis; Request for Assistance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) seeks additional information on issues related to clinical development programs for human drugs, biological products, and medical devices for the treatment and prevention of osteoarthritis (OA). We will take such information into account as we work to finalize our draft guidance issued in July 1999. Once finalized, the guidance will aid sponsors and other interested parties in developing new products to treat OA.

Before the agency can issue such guidance, a critical appraisal of certain fundamentals of the science related to OA is needed. FDA is inviting any interested party, or parties, to conduct and manage the coordination of this critical appraisal. FDA believes that the party, or parties', first step in conducting the critical appraisal would be to hold a public meeting to discuss issues related to OA assessment and trial design. FDA intends to submit to the docket all the information received in response to this notice so that interested parties may be fully informed and to facilitate participation in and coordination of these activities.

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