Stat. 770, 774 (1974) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: March 23, 1999.

Wendy M. Comes,

Executive Director.

[FR Doc. 99–7480 Filed 3–25–99; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Arthritis 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 April 20 and 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker and Whetstone Rooms, Two Montgomery Village Ave, Gaithersburg, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, 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, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 21–042 Vioxx™ (rofecoxib, Merck) for the treatment of acute or chronic signs and symptoms of osteoarthritis and the management of pain.

Procedure: On April 20, 1999, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 April 14, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 1999, 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.

Closed Committee Deliberations: On April 21, 1999, from 8 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: March 16, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–7362 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Changing Times; Clinical Trial Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Southeast Region, is announcing the following meeting: ''Changing Times: Clinical Trial Regulations, Clinical Investigators and IRB's Learning to Cope.'' The topic to be discussed is FDA regulatory requirements for the conduct of clinical studies and practical issues such as how clinical investigators and Institutional Review Boards can cope with the regulatory process, how to prepare for a data audit, what to expect during an inspection, and how to get current information from FDA.

Date and Time: The meeting will be held on Friday, April 30, 1999, from 8 a.m. to 6 p.m.

Location: The meeting will be held at the Veterans Administration Medical Center Auditorium (2d floor), 1201 NW. 25th St., Miami, FL 33125.

Contact: Luz I. Collado, Food and Drug Administration, HFR–SE2575, P.O. Box 59–2256, Miami, FL 33159, 305–526–2800, ext. 926, or Brunilda Torres, Food and Drug Administration, Florida District, HFR–SE250, 407–475–4718, FAX 407–475–4768.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Gloria Allington, Director, University of Miami School of Medicine, Division of Continuing Medical Education, 1500 NW. 12th Ave., Miami, FL 33136, 305–243–6716, FAX 305–243–5613. Attendance will be limited to the first 200 applicants, therefore, interested parties are encouraged to register early. A $100 registration fee is being charged by the University of Miami School of Medicine to help cover costs of materials, breakfast, box lunches, and beverages for breaks. A discounted registration fee of $90 is being offered to those who register by Thursday, April 1, 1999.

If you need special accommodations due to a disability, please contact Gustavo Godoy, Executive Director and Administrative Officer for R&D, VA Medical Center, 1201 NW. 16th St., Miami, FL 33125, 305–324–3179, FAX 305–324–3126, at least 7 days in advance.

Dated: March 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7361 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0484]

Draft Guidance for Industry on Accelerated Approval Products: Submission of Promotional Materials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval Products: Submission of Promotional Materials.'' The accelerated approval regulations require that applicants, unless otherwise informed by the agency, submit to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling and advertisements, intended for dissemination or publication within 120 days following marketing approval. This draft guidance is intended to assist sponsors of drug and biological products who are submitting such materials as part of the accelerated approval process.

DATES: Written comments on the draft guidance may be submitted by May 26, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'', or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or FAX 301–594–3215.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Tracy L. Acker, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2831, or via Internet at ackert@cder.fda.gov.

Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Accelerated Approval Products: Submission of Promotional Materials.'' This draft guidance is intended to assist sponsors of drug and biological products who are submitting promotional materials as part of the accelerated approval process.

In the **Federal Register** of December 11, 1992 (57 FR 58942), FDA published final regulations under which the agency would accelerate the approval of certain new drugs and biological products for serious or life-threatening illnesses. In November 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Pub. L. 105–115). Section 112 of the Modernization Act, in part, essentially codified in statute the accelerated approval regulations in an amendment to the Federal Food, Drug, and Cosmetic Act (section 506 of the act (21 U.S.C. 356) entitled ''Fast Track Products''). On November 12, 1998, FDA published a draft guidance for industry on its policies and procedures regarding fast track drug development programs. The draft guidance that is the subject of this notice would apply to all products approved under § 314.500 (21 CFR 314.500), including those designated as fast track development programs.

Among other things, the accelerated approval regulations (§§ 314.550 and 601.45 (21 U.S.C. 314.550 and 601.45)) require that applicants, unless otherwise informed by the agency, submit to FDA for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication during the 120 days following marketing approval. The accelerated approval regulations also require that promotional materials intended for use following the 120-day postapproval period must be submitted to FDA for review at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement, unless otherwise informed by the agency.

During the past several years, representatives of the pharmaceutical industry have requested guidance from FDA on the procedures for submitting promotional materials under §§ 314.550 and 601.45. The draft guidance is intended to assist applicants submitting promotional materials under these regulations.

This draft guidance document represents the agency's current thinking on the process for submitting promotional materials for accelerated approval 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 requirement of the applicable statute, regulations, or both.

Interested persons may, on or before May 26, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments or requests for copies are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 19, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–7516 Filed 3–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Number 99D–0392]

Seafood HACCP Transition Guidance; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing for comment draft guidance setting forth circumstances under which the agency may consider refraining from regulatory action under the seafood Hazard Analysis Critical Control Point (HACCP) regulation and the Federal Food, Drug, and Cosmetic Act (the act) pending completion of studies to resolve scientific issues relating to whether the agency should revise or amend its policies concerning particular hazard analyses or controls.

DATES: Submit written comments by May 26, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should contain the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

SUPPLEMENTARY INFORMATION: On December 18, 1995 (60 FR 65096), FDA published final regulations (21 CFR part 123) that require processors of fish and fishery products to develop and implement HACCP systems for their operations. Those regulations became effective on December 18, 1997. As a companion to the regulation, FDA also issued a guidance document entitled the Fish and Fishery Products Hazards and Controls Guide (the Guide). The Guide contains FDA's compilation of what the agency believes to be the latest, science-based knowledge about when food safety hazards are reasonably likely to occur and what controls are appropriate for those hazards. In the period since the publication of the final regulations, FDA has produced two editions of the Guide. The agency intends to publish