FOR FURTHER INFORMATION CONTACT: Minnie Johnson, Antibiotic Resistance, NCID, CDC, M/S C–20, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–2603, fax 404/639–4139, E-mail: mlj2@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 21, 1999.

Carolyn J. Russell,

Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–16298 Filed 6–25–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for Prevention Research Centers, Program Announcement #98047, meeting.

Times and Dates:

9 a.m.–5 p.m., July 12, 1999 (Closed).
8 a.m.–9 a.m., July 13, 1999 (Open).
9 a.m.–5 p.m., July 13, 1999 (Closed).
8 a.m.–5 p.m., July 14, 1999 (Closed).
8 a.m.–5 p.m., July 15, 1999 (Closed).
8 a.m.–5 p.m., July 16, 1999 (Closed).

Place: Sheraton Colony Square Hotel, 188 14th St., NE, Atlanta, GA. Telephone 404/892–6000.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #98047.

This notice is being published less than 15 days prior to the meeting, due to administrative delays.

Contact Person for More Information: Marshall Kreuter, Ph.D., Associate Director for Health Promotion, Policy and Program Development, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, 3005 Chamblee Tucker Rd., Atlanta, GA., 30341–4133. Telephone 770/488–5832. E-mail *mak2@cdc.gov.*

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 21, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 99–16297 Filed 6–25–99; 8:45 am]

BILLING CODE 4163–18–P

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). The meeting will be open 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 July 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Salons, 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 email reedyk@cder.fda.gov 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 evidence needed to establish that a drug product has a beneficial effect on joint structure in patients with osteoarthritis.

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 by July 12, 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 July 12, 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.

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

Dated: June 18, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–16314 Filed 6–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 July 26, 1999, 10:30 a.m. to 5 p.m., and July 27, 1999, 7:30 a.m. to 2:30 p.m.

Location: Hilton Hotel, Salons B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Hany W. Demian or Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 27, 1999, the committee will discuss and make recommendations on the classification of bone dowel devices of human origin.

Procedure: On July 27, 1999, from 7:30 a.m. to 2:30 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 July 16, 1999. Oral presentations from the public regarding the classification of bone dowel devices will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on July 27, 1999. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by July 16, 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 July 26, 1999, from 10:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information on a product development protocol. This portion of the meeting will be closed to permit discussion of this 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: June 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–16315 Filed 6–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Draft Guidance for Industry on Changes to an Approved NDA or ANDA; 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 ''Changes to an Approved NDA or ANDA.'' This draft guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under the proposed revision to the drug regulations pertaining to supplements and other changes to an approved application published elsewhere in this issue of the **Federal Register**.

DATES: Written comments may be submitted on the draft guidance document by August 27, 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''. 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 the 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.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Changes to an Approved New Drug (NDA) or Abbreviated New Drug (ANDA) Application.''

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pub. L. 105–115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. FDA is proposing to amend its regulations entitled *Supplements and other changes to an approved application* at § 314.70 (21 CFR 314.70) to conform to section 506A of the act. This proposed rule is published elsewhere in this issue of the **Federal Register**.

The purpose of this draft guidance is to provide recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 314.70. This draft guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes. This guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

The guidance document, which cites the proposed rule for amending § 314.70, will be revised based on public comments and implemented for use as a companion document to § 314.70 when the rule is finalized. FDA welcomes comments that provide additional examples of major, moderate, and minor changes.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This guidance document represents the agency's current thinking on reporting categories for postapproval changes of drugs, other than specified biotechnology and specified synthetic biological 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 submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.