Control and Prevention (CDC) announces the following meeting.

NAME: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Community Coalition Development Projects for African American Communities, PA#01033, meeting.

TIMES AND DATE: 9 a.m.–1 p.m., July 23, 2001 (Open); 1 p.m.–2 p.m., July 23, 2001 (Closed); 8:30 a.m.–4:30 p.m., July 24, 2001 (Closed); 8:30 a.m.–8:45 a.m., July 25, 2001 (Open); 8:45 a.m.–4:30 p.m., July 25, 2001 (Closed)

PLACE: The Westin Atlanta North at Perimeter, 7 Concourse Parkway, Atlanta, GA 30328.

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 Deputy Director for Program Management, 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 01033.

CONTACT PERSON FOR MORE INFORMATION: Elizabeth A. Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 8 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639–8025.

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: July 2, 2001.

Carolyn J. Russell,

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

[FR Doc. 01–17042 Filed 7–6–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0269]

Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' The agency has initiated a comprehensive effort to improve the format and content of prescription drug labeling. FDA intends to carefully coordinate development and implementation of these labeling initiatives to minimize the potential burden for manufacturers and other affected parties.

DATES: Submit written comments on the draft guidance by October 9, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 1–888–CBERFAX, or Voice Information System at 800–835–4709 or 301–827–1800. 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Janet M. Jones, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or

Toni Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. Recently the agency published a proposed rule to revise the overall format of prescription drug labeling (65 FR 81082, December 22, 2000). Among other things, the agency proposed reordering the sections of the labeling based on the importance of the information to practitioners and the frequency with which practitioners refer to a section. Also, the agency proposed creating a ''highlights'' section and an index.

FDA is working on a proposed rule to revise the current requirements for the pregnancy subsection of labeling (see the notice (62 FR 41061, July 31, 1997) announcing a 21 CFR part 15 hearing to discuss the category requirements, and the notice (64 FR 23340, April 30, 1999) announcing a meeting of a public advisory committee to discuss possible changes to pregnancy labeling).

The agency also is developing guidance documents that focus on the content of certain labeling sections. The first draft guidance, ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics,'' was made available for public comment on June 21, 2000 (65 FR 38563). This draft guidance, ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format,'' is the second guidance document on the content and format of individual labeling sections. Among other things, this draft guidance discusses what studies to include in the Clinical Studies section, how to describe those studies, and how to present clinical study data in graphs and tables. The agency also is trying to raise awareness, with this draft guidance, of the implications for product promotion of information contained in the Clinical Studies section. This section exists in the current labeling and is expected to continue to exist when the proposed rule to revise the format for prescription drug labeling is made final.

At this time, FDA is also developing guidances for the Adverse Reactions, Clinical Pharmacology, and Warnings/Precautions sections of the labeling. The draft guidance for the Adverse Reactions section was made available for public comment on June 21, 2000 (65 FR 38563). The agency expects to publish draft guidances for the Clinical Pharmacology and Warnings/Precautions sections for comment in the

coming months. The agency has focused its efforts on these sections of the labeling because they typically contain large amounts of important and complex information, and there have been significant differences in their format and content across product classes and individual medical products. Guidances for other labeling sections may be developed later.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on the content and format of the Clinical Studies section of labeling for human prescription drugs and biologics. 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 can be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may 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 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or at http://www.fda.gov/cber/guidelines.htm.

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17048 Filed 7–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1033]

Draft Guidance for Industry on Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan; 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 ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan.'' The draft guidance discusses procedures for submission of protocol information to the Clinical Trials Data Bank established under section 113 of the Food and Drug Administration Modernization Act (Modernization Act), which required the establishment of this data bank and specified what information was to be submitted for it. Procedural issues discussed in this guidance document were not included in an earlier draft guidance document on the scope of the Data Bank, which published in the **Federal Register** on March 29, 2000 (65 FR 16620).

DATES: Submit written comments on the draft guidance by September 7, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBER–FAX. 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. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Theresa Toigo, Center for Drug Evaluation and Research (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Description of Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan.'' The draft guidance is intended to provide recommendations for sponsors of investigational new drug applications (INDs) on how to submit information about clinical trials for serious or life-threatening diseases to a clinical trials data bank developed by the National Library of Medicine (NLM), National Institutes of Health (NIH).

The Modernization Act (Pub. L. 105–115), enacted on November 21, 1997, amends section 402 of the Public Health Service Act (42 U.S.C. 282) and directs the Secretary of Health and Human Services (the Secretary), acting through the Director, NIH, to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (hereafter referred to as the Clinical Trials Data Bank).

The Clinical Trials Data Bank is intended to be a central resource, providing current information on clinical trials to individuals with serious or life-threatening diseases, to other members of the public, and to health care providers and researchers. Specifically, the Clinical Trials Data Bank will contain information about both federally and privately funded studies of experimental treatments for patients with serious or life-threatening diseases conducted under FDA's IND regulations (21 CFR part 312).

The NIH, through NLM and with input from FDA and others, developed the Clinical Trials Data Bank and is implementing it in a phased approach. The first version of the Clinical Trials Data Bank was made available to the public on February 29, 2000, on the Internet at http://clinicaltrials.gov. It included primarily NIH-sponsored trials.

In the **Federal Register** of March 29, 2000, FDA published a draft guidance entitled ''Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank.'' The March 29, 2000, draft guidance provided recommendations for industry on the submission of protocol information to the Clinical Trials Data