4. Project Management and Staffing (15 points)

The extent to which the applicant identifies staff that have the responsibility, capability, and authority to carry out each activity, as evidenced by job descriptions, curriculum vitae, and organizational charts.

5. Sharing Experiences and Resources (5 points)

The extent to which the applicant describes plans to share effective materials and activities with appropriate audiences.

6. Collaboration (5 points)

The extent to which the applicant describes plans to collaborate with agencies such as state and local health and education departments, postsecondary institutions, and other national organizations and provides letters of specific intentions from collaborating agencies.

7. Evaluation (10 points)

The quality of the plans for both process and outcome evaluations, to include specification of indicators of program success, methods of obtaining data, ways of reporting results, use of results for programmatic decisions, and timing and staff responsibility.

8. Budget (Not Scored)

The extent to which the applicant provides a detailed and clear budget narrative consistent with the stated objectives, planned activities, and goals of the project.

H. Other Requirements

1. Technical Reporting Requirements

Provide Center for Disease Control with original plus two copies of:

a. Annual progress reports, no more than 90 days after the end of each budget period;

b. Financial status reports, no more than 90 days after the end of the budget period; and

c. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in section J, ''Where to Obtain Additional Information''.

2. Research Activities Restricted

Activities funded under this program announcement are intended to build the capacity of postsecondary institutions to promote HIV, other STDs, and unintended pregnancy prevention and to prevent other serious health problems among youth and young adults as described in the two priority areas. Research activities will not be supported under this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III in the application kit.

AR–5—HIV Program Review Panel Requirements
AR–7—Executive Order 12372 Review
AR–8—Public Health System Reporting Requirements
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions
AR–15—Proof of Non-profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317(k)(2) and 1706 [42 U.S.C. 241(a), 247b(k)(2) and 300u–5] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.938.

J. Where to Obtain Additional Information

This and other Center for Disease Control announcements can be found on the Center for Disease Control home page <www.cdc.gov>. Click on Funding then click on Grants and Cooperative Agreements. To receive additional written information and to request an application kit, call (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the announcement of interest.

If you have questions after reviewing the contents of all documents, business management assistance may be obtained from: Van A. King, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00081, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146; Telephone Number (770) 488–2751; Email address vbk5@cdc.gov.

For program technical assistance, contact: Mary Vernon-Smiley, Chief, Special Populations Program Section, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS K–31, Atlanta, Georgia 30341–4146; Telephone Number (770) 488–325–8004; Email address mev0@cdc.gov.

Dated: May 31, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–14098 Filed 6–5–00; 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 12, 2000, 8 a.m. to 5 p.m.

Location: Gaithersburg 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 e-mail: 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 biologics license application (BLA) 99–1234, Remicade™ (infliximab, Centocor) for the treatment of rheumatoid arthritis, prevention of radiographic progression and prevention of physical disability. The Committee will also discuss general issues regarding claims based on radiographic data in patients with rheumatoid arthritis.

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 6, 2000. 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 6, 2000, 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: May 31, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–14213 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0965]

''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components.'' The guidance document describes a system for the uniform labeling of blood and blood components for transfusion, Source Plasma, and other components for use in further manufacturing. The guidance will assist manufacturers in complying with the labeling requirements under FDA's regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For information about this notice: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

For technical information: Kenneth A. Zemann, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3543, or FAX 301–827–3534.

SUPPLEMENTARY INFORMATION:

I. Background

The International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA a draft document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*,'' Version 1.2.0 (draft Standard). The ICCBBA requested that ISBT 128 replace the current ''ABC Codabar'' system as an approved machine readable barcode for labeling blood and blood components. On November 21, 1998, FDA made the draft Standard available on its website for public comment. In the **Federal Register** of November 27, 1998 (63 FR 65600), FDA announced the availability of the draft Standard and requested public comment on both the use of ISBT 128 and timeframes for implementation. The ICCBBA revised the draft Standard in response to public comment and submitted to FDA the revised document entitled ''United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128*,'' Version 1.2.0, dated November 1999 (the Version 1.2.0 Standard).

FDA has reviewed the draft Standard, the comments received, and the Version 1.2.0 Standard. FDA believes that conformance to the Version 1.2.0 Standard, prepared and revised by ICCBBA, will help facilitate the use of a uniform container label for blood and blood components. FDA is announcing the availability of a guidance entitled ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components'' that recognizes as acceptable the Version 1.2.0 Standard prepared by ICCBBA, and the implementation of the ISBT 128 uniform labeling system, except where inconsistent with FDA's regulations under 21 CFR 606.121. Although FDA finds use of the Version 1.2.0 Standard acceptable, FDA has identified inconsistencies between the Version 1.2.0 Standard and Federal regulations. FDA intends to revise the regulations to remove these inconsistencies. The guidance provides recommendations to follow where discrepancies exist between the Version 1.2.0 Standard and the current regulations, pending completion of rulemaking to remove these discrepancies.

This guidance document represents the agency's current thinking with regard to use of the Version 1.2.0 Standard for use in labeling blood, blood components for transfusion, Source Plasma, and other components for further manufacturing use. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document at any time. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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. Paperwork Reduction Act of 1995

The labeling regulations on which the guidance is based are reported under the Office of Management and Budget (OMB) control number 0910–0116. FDA tentatively concludes that this guidance contains no new collections of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.