The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 99–31054 Filed 11–29–99; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Secretary, DHHS.

ACTION: Notice of meeting.

The Advisory Committee on Blood Safety and Availability will meet on Wednesday, January 26, 2000, from 9:00 a.m. to 5:00 p.m. and on Thursday, January 27, 2000 from 9:00 a.m. to 3:00 p.m. The meeting will take place at the Hyatt Regency Hotel On Capitol Hill, 400 New Jersey Ave., NW, Washington, DC 20001. The meeting will be entirely open to the public.

The topic of the meeting will be errors and accidents in blood administration and what might be done to reduce the occurrence of these events.

Public comment will be solicited both days. Public comment will be limited to three minutes per speaker. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business January 12, 2000.

FOR FURTHER INFORMATION CONTACT: Stephen D. Nightingale, M.D., Executive Secretary, Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, Office of Public Health and Safety, 200 Independence Avenue SW, Rm 736E, Washington, DC 20201. Phone (202) 690–5560 FAX (202) 690–7560 e-mail stephendnightingale@osophs.dhhs.gov.

Dated: November 19, 1999.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 99–30981 Filed 11–29–99; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Implementation of Universal Leukoreduction; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Workshop on Implementation of Universal Leukoreduction.'' The purpose of the public workshop is to stimulate public discussion on how to implement pre-storage leukoreduction as a routine step in the manufacture of whole blood, red blood cells, and platelets that are intended for human transfusion.

Date and Time: The public workshop will be held on December 10, 1999, 8:30 a.m. to 4:45 p.m.

Location: The public workshop will be held at the National Institutes of Health, Natcher Conference Center, 45 Center Dr., Bldg. 45, Bethesda, MD.

Contact: For information regarding this notice: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6129, FAX 301–827–2843. For information regarding the public workshop and registration: Jennifer Gormley, Laurel Consulting Group, 1815 Fort Meyer Dr., suite 300, Arlington, VA 22209, 703–351–7676, FAX 703–528–0716, E-mail: jgormley@lcgnet.com.

Registration: Early registration is recommended on or before December 3, 1999. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Jennifer Gormley (address above). Registration at the site will be on a space available basis on the day of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Jennifer Gormley at least 7 days in advance.

Agenda: FDA anticipates that the ideas and experiences exchanged at the workshop will serve as a source of information for the blood industry and the public in planning for universal leukoreduction, as well as guide FDA in formulating specific regulatory recommendations. Issues to be discussed include: (1) The experiences in implementing leukoreduction as a routine blood manufacturing step and in the use of leukocyte reduced blood products; (2) whether and in what timeframe universal leukoreduction should be recognized as a blood manufacturing standard; and (3) what experiences exist to date in the United States with respect to implementing leukoreduction as a routine blood manufacturing step. An open panel discussion will include a critique of the experiences in the United States to date in implementing leukoreduction as a routine blood manufacturing step, as well as proposals for the FDA to consider in formulating new blood recommendations and regulations. All members of the transfusion community are encouraged to participate with the understanding that the workshop will focus on operational issues, rather than scientific, clinical and economic merits of universal leukoreduction.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16,Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA Internet site at www.fda.gov/cber/minutes/workshop-min.htm.

Dated: November 23, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–30956 Filed 11–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4959]

Guidance for Industry on the Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000.'' This

document provides guidance for industry on how FDA interprets the Federal Advisory Committee Act (FACA) with respect to the disclosure of materials provided to advisory committees convened by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted on the guidance document by February 28, 2000. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance 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 this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000.'' The document provides guidance on how FDA interprets the FACA (5 U.S.C. App. 2) and § 314.430 (21 CFR 314.430) with respect to the disclosure of materials provided to advisory committees and how FDA will exercise its discretion under § 314.430(d)(1) in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

FDA construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the Freedom of Information Act (FOIA) (5 U.S.C. 552), those materials that are provided to the members of an advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. FDA interprets § 314.430 to be consistent with the FACA and therefore will exercise its discretion under § 314.430(d)(1) in a manner consistent with the FACA and the FOIA as described in the previous sentence to make available for public inspection and copying materials provided to the members of an advisory committee in connection with open advisory committee meetings convened by CDER, beginning on January 1, 2000.

FDA will issue further guidance on what sponsors may expect concerning the disclosure of the materials they submit to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance is needed to implement a court-approved settlement agreement. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

The guidance represents the agency's current thinking on the disclosure of materials provided to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000. 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 requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the 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 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.

Dated: November 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30955 Filed 11–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Antitumor and Antimicrobial Lead—Discovery and Development From Natural Products

Opportunities for Cooperative Research and Development Agreements (CRADAs) are available for collaborations with the NCI intramural Laboratory of Drug Discovery Research and Development (LDDRD) to discover and identify novel antitumor and antimicrobial leads from natural products. Collaborative projects will focus upon cancer and/or areas of infectious diseases of high public health significance and high national and international priority.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for Cooperative Research and Development Agreements (CRADAs).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks one or more Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to discover and develop new potential antitumor and/or antimicrobial drug leads from natural products. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Development & Commercialization Branch, National Cancer Institute—Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick,