1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3297 Colorants for polymers (21 CFR 178.3297) to provide for the safe use of N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxy-2-naphthalenecarboxamide] as a colorant for food-contact polymers. Ciba-Geigy Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: February 9, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–4715 Filed 2–29–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its clinical hold review committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in May 1996. Biological product companies may submit review requests for the May meeting by April 1, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting a review committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The committee last met in February 1996. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, 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. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its May 1996 meeting. Submissions should be made by April 1, 1996, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: February 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4785 Filed 2–29–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 Availability of Funds for Early Intervention Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Pre-Application Technical Assistance Workshops.

SUMMARY: The Health Resources and Services Administration will hold two pre-application technical assistance workshops for competing applicants under Title III(b), HIV Early Intervention Services, of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Public Law 101–381.

Eligible applicants are public entities and nonprofit private entities that are: Migrant health centers under Section 329 of the PHS Act; community health centers under Section 330 of the PHS Act; health care for the homeless grantees under Section 340 of the PHS Act; family planning grantees under Section 1001 of the PHS Act other than States; comprehensive hemophilia diagnostic and treatment centers; federally-qualified health centers under section 1905(1)(2)(B) of the Social Security Act; or public and private nonprofit entities that currently provide comprehensive primary care services to populations at risk of HIV disease.

PURPOSE: The purpose of the technical assistance workshops is to provide information about the Ryan White CARE Act Early Intervention Services program and application procedures. Eligible entities will have an opportunity to review the program guidance and to receive technical assistance pertaining to all aspects of writing a grant applications.

FOR FURTHER INFORMATION CONTACT: Anyone interested in attending the meetings should contact Ms. Andrea Kay, Professional and Scientific Associates, Inc., 8180 Greensboro Drive, Suite 1050, McLean, VA 22102. She may be reached by telephone at 703–442–9824 or by fax at 703–442–9826. Room reservations should be made directly with the hotel. Costs of attending the workshop are the sole responsibility of the attendee.

DATE, TIME, LOCATION:

Thursday, March 14, 1996, 9:00 a.m.–5:00 p.m., Radisson Hotel Dallas, Dallas, Texas, 214–634–8850

Friday, March 22, 1996, 9:00 a.m.–5:00 p.m., Doubletree Hotel, Rockville, Maryland, 301–468–1100

The OMB Catalog of Federal Domestic Assistance number for this program is 93.918.

Dated: February 26, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–4720 Filed 2–29–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Cancer Institute Notice of Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Cancer Institute Board of Scientific Advisors and the Board of Scientific Counselors, National Cancer Institutes on March 21, 1996 at the National Institutes of Health, 9000 Rockville Pike Building 31, C Wing, 6th Floor, Conference Rooms 10, 9 and 8, Bethesda, MD 20892.

A joint session of the two committees will be open to the public in Conference Room 10 from 8:30 am to 12:30 pm for orientation of members.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. for discussion of confidential issues relating to the review and evaluation of individual programs and projects. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Committee Name: National Cancer Institute Board of Scientific Advisors.

Closed: March 21, 1996, 12:30 to 5:00 pm.

Agenda: To discuss confidential issues relating to the review and evaluation of individual extramural programs and projects.

Committee Name: Board of Scientific Counselors, National Cancer Institute.

Closed: March 21, 1996, 12:30 to 5:00 pm.

Agenda: To discuss administrative confidential site visit reports pertaining to laboratories in the Divisions of Basic and Clinical Sciences.

Information pertaining to the meetings may be obtained from Dr. Paulette Gray, Executive Secretary, National Cancer Institute Board of Scientific Advisors, National Cancer Institute, 6130 Executive Blvd., EPN, Rm 600, Bethesda, MD 20892, (301–496–4218). Individuals who plan to attend the open session and need special assistance such as sign language interpretation or other reasonable accommodations should contact Dr. Paulette Gray in advance of the meeting.

Dated: February 23, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–4746 Filed 2–29–96; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Notice of a Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Review on the Early Natural History of Arteriosclerosis.

Date: March 28, 1996.

Time: 11 a.m.

Place: DoubleTree Hotel, 300 Army Navy Drive, Arlington, Virginia.

Contact Person: C. James Scheirer, Ph.D., Two Rockledge Center, Room 7220, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0266.

Purpose/Agenda: To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: February 26, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–4742 Filed 2–29–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis panel (SEP) meeting:

Name of SEP: Cooperative Clinical Trial in Adult Transplantation.

Date: March 21, 1996.

Time: 10:30 a.m.

Place: Solar Bldg., Room 4A07, 6003 Executive Boulevard, Bethesda, MD 20892.