regular basis, the CDRH home page includes the draft guidance document entitled ''Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The guidance document entitled ''Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices'' will be available at http://www.fda.gov/cdrh/draftgui.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before July 27, 1998, submit to Dockets Management Branch (address above) written comments regarding this draft guidance.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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 1998.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–11158 Filed 4–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0233]

Guidance for Industry on PAC–ATLS: Postapproval Changes—Analytical Testing Laboratory Sites; 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 ''PAC–ATLS: Postapproval Changes—Analytical Testing Laboratory Sites.'' This guidance provides recommendations to pharmaceutical sponsors of new drug applications (NDA's) and abbreviated new drug applications (ANDA's) who intend to change an analytical testing laboratory site for components, drug product containers, closures, packaging materials, in-process materials, or drug products during the postapproval period. This guidance is intended to ease the burden of notification, under certain circumstances, for analytical testing laboratory site changes currently requiring prior approval supplements under the human drug regulations.

DATES: Written comments may be submitted 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 the guidance for industry entitled ''PAC–ATLS: Postapproval Changes—Analytical Testing Laboratory Sites,'' 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 the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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, 301–594–5629.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''PAC–ATLS: Postapproval Changes—Analytical Testing Laboratory Sites.'' This guidance is intended to ease the burden of notification, under certain circumstances, for analytical testing laboratory site changes currently requiring prior approval supplements under § 314.70 (21 CFR 314.70). FDA regulations at § 314.70(a) provide that applicants may make changes to an approved application in accordance with a guidance, notice, or regulation published in the **Federal Register** that provides for a less burdensome notification of the change (for example, by notification at the time a supplement is submitted or in the next annual report).

This guidance for industry represents the agency's current thinking on postapproval changes in analytical testing laboratory sites. 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, at any time, 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: April 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–11198 Filed 4–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Environmental Health Sciences Council, May 18–19, 1998, Building 31, Conference Room 10, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public from 8:30 a.m. to approximately 3:20 p.m. on May 18 for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and

issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. and sec. 10(d) of Pub L. 92–463, the meeting will be closed to the pubic from approximately 3:30 p.m. on May 18 to adjournment at 5:00 p.m. and on May 19 from 9:00 a.m. until adjournment at 12:00 p.m., for the review, discussion, and evaluation of individual grant application. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Anne Sassaman, Director, Division of Extramural Research and Training, and Executive Secretary, National Advisory Environmental Health Sciences and Council, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709, (919) 541–7723, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: April 21, 1998.

LaVeen Ponds,

Policy Analyst, NIH.

[FR Doc. 98–11250 Filed 4–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed 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 National Heart, Lung, and Blood Institute Special Emphasis Panel (SEP) meetings:

Name of SEP: Cardiovascular Benefits of Soy Phytoestrogens.

Date: May 4–5, 1998.

Time: 7:00 p.m.

Place: Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20879.

Contact Person: Anthony M. Coelho, Ph.D, Two Rockledge Center, Room 7194, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0288.

Purpose/Agenda: To review and evaluate grant applications.

This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the grant review and funding cycle.

Name of SEP: Lipoprotein(a) Standardization Program (Telephone Conference Call).

Date: May 20, 1998.

Time: 2:00 p.m. EDT.

Place: Two Rockledge Center, Room 7214, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Camille King, Ph.D, Two Rockledge Center, Room 7208A, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0321.

Purpose/Agenda: To review and evaluate contract proposals.

Name of SEP: Review of Independent Scientist Award (K02) and Mentored Clinical Scientist Development Award (K08) Applications.

Date: June 15, 1998.

Time: 8:00 a.m.

Place: Key Bridge Marriott, 1401 Lee Highway, Arlington, Virginia 22209.

Contact Person: S. Charles Selden, Ph.D, Two Rockledge Center, Room 7196, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0288.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Public Access Defribrillation (PAD–1) Clinical Trial.

Date: June 23, 1998.

Time: 8:00 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Contact Person: Joyce A Hunter, Ph.D, Two Rockledge Center, Room 7192, 6701 Rockledge Drive, Bethesda, MD 20892–7924, (301) 435–0287.

Purpose/Agenda: To review and evaluate contract proposals.

These meetings will be closed in accordance with the provisions set forth in secs. 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: April 21, 1998.

LaVeen Ponds,

Policy Analyst, NIH.

[FR Doc. 98–11253 Filed 4–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of SEP: Genotypic & Phenotype Heterogenity in Dyslexia.

Date: May 7, 1998.

Time: 9:00 a.m.—adjournment.

Place: 6100 Executive Boulevard, DSR Conference Room, Rockville, Maryland 20852.

Contact Person: Scott Andres, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, Room 5E01, Rockville, MD 20852, Telephone: 301–496–1485.

Purpose/Agenda: To evaluate and review a research grant application.

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. The discussion of this application could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with this application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. [93.864, Population Research and No. 93.865, Research for Mothers and Children], National Institute of Health, HHS)

Dated: April 21, 1998.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 98–11251 Filed 4–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the