regular basis, the CDRH home page includes the draft guidance document entitled ''Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications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may, on or before July 27, 1998, submit to Dockets Management Branch (address above) written comments regarding this draft guidance.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