and in sections VI and VII of the SUPAC–MR guidance.

This draft guidance represents the agency's current thinking on scale-up and postapproval equipment changes for immediate release and modified release solid oral dosage forms regulated by CDER. 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.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–11197 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–0238]

Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices.'' This guidance is not final or in effect at this time. The purpose of this document is to suggest to the device manufacturer or investigation sponsor important information which should be presented in investigational device exemption (IDE) and premarket approval (PMA) applications in order to provide reasonable assurance of the safety and effectiveness of these devices for their intended uses.

DATES: Written comments concerning this guidance must be submitted by July 27, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications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'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this guidance document must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

The preparation of a guidance document for Bone Growth Stimulator applications was first initiated by the Division of Surgical and Rehabilitation Devices (DSRD) of the Office of Device Evaluation (ODE) in conjunction with the Division of Physical Sciences (DPS) and Life Sciences (DLS) of the Office of Science and Technology in 1985. The purpose of the document was to suggest to the device manufacturer or investigation sponsor important information which should be presented in IDE and PMA applications in order to provide reasonable assurance of the safety and effectiveness of these devices for their intended uses. The document went through extensive review by representatives of DSRD, DPS, DLS, the Orthopedic and Rehabilitation Devices (ORD) Advisory Panel, and industry representatives. Comments and recommendations generated by these reviews resulted in a revised draft document, which was presented for discussion during an open public session of the ORD Advisory Panel meeting held on October 31, 1986. Subsequent to the panel meeting, the Health Industry Manufacturers Association organized a task force which again reviewed the document and suggested changes to the Center for Devices and Radiological Health (CDRH) on February 15, 1988. As a result, a final guidance document was issued on August 12, 1988. This revised draft of the guidance document was initiated in response to discussions and correspondences with sponsors of bone growth stimulator devices and other interested parties, and it provides additional guidance detailing the ODE's present perspective on issues relating to these devices. The revised draft guidance will be considered by the ORD Advisory Panel in a meeting to be held on April 28, 1998, at 9200 Corporate Blvd., Rockville, MD.

II. Significance of Guidance

This guidance document represents the agency's current thinking on IDE and PMA applications for Bone Growth Stimulators. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive copies of 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'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (487) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a

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]

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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