Dated: February 12, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–3890 Filed 2–15–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 5, 2001, 9 a.m. to 3:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a computer-aided detection device for identifying regions of interest in chest radiographs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 26, 2001. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m., and for an additional 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2001.

Bonnie H. Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–4033 Filed 2–15–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D 0994]

Guidance for Industry on BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation; 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 ''BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation.'' This guidance provides recommendations to holders of new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and drug master files or veterinary master files who intend, during the postapproval period, to change the site of manufacture, the scale of manufacture, the equipment, the specification(s), and/or the manufacturing process of intermediates in the synthetic pathway leading to the drug substance.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: 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 the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kasturi Srinivasachar, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5376; or Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation.'' This guidance describes chemistry, manufacturing, and controls information and documentation in support of each change and provides recommendations on reporting categories. The guidance applies to synthetic drug substances and the synthetic steps involved in the preparation of semisynthetic drug substances. It is limited to structurally well-characterized drug substances where impurities can be monitored at the levels recommended. The guidance covers changes as follows: (1) Site, scale, and equipment changes involving the synthetic steps up to, and including, the step that produces the final intermediate; (2) specification changes for raw materials, starting materials, and intermediates, excluding the final intermediate; and (3) manufacturing process changes involving the synthetic steps up to and including the final intermediate. The guidance does not cover postapproval changes affecting: (1) Synthetic peptides, (2) oligonucleotides, (3) radiopharmaceuticals, (4) drug substances derived exclusively by isolation from natural sources or produced by procedures involving biotechnology, or (5) nonsynthetic steps for semisynthetic drug substances. Also excluded from this guidance are certain changes in specification and process associated with the use of raw materials or starting materials derived from natural sources or biotechnology.

In the **Federal Register** of November 30, 1998 (63 FR 65793), FDA announced the availability of a draft version of this guidance. The November 1998 guidance gave interested persons an opportunity to submit comments through March 31, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. As a result of the public comment, the guidance is clearer and more concise than the draft version.

This Level 1 guidance is being issued consistent with FDA's good guidance