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]

BILLING CODE 4160–01–F

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

practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on intermediates in drug substance synthesis, bulk actives postapproval changes, chemistry, manufacturing, and controls documentation. 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 statutes and regulations.

II. Comments

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 guidance. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cvm.

Dated: February 8, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–3956 Filed 2–15–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1313]

Guidance for Industry on How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final guidance for industry (#86) entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' to the Center for Veterinary Medicine (CVM). This final guidance provides guidelines to new animal drug sponsors (sponsors) on how to submit a notice of final disposition of animals not intended for immediate slaughter (NFDA) as an e-mail attachment by Internet. This electronic submission is part of CVM's ongoing initiative to provide a method for paperless submissions. This final guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments on the final guidance at any time.

ADDRESSES: Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the final guidance and the docket number found in brackets in the heading of this document.

Copies of the final guidance document entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/. Persons without Internet access may submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2000 (65 FR 40104), FDA published the notice of availability of the draft guidance entitled ''How to Use E–Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter'' (hereinafter referred to as the June 2000 notice). Interested persons were given until August 28, 2000, to submit comments. FDA received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the Electronic Records; Electronic Signatures final regulation. This regulation (21 CFR part 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established docket number 92S–0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. The docket is accessible on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251.htm. CVM will identify in this public docket the types of documents that may be submitted in electronic form as those documents are identified in final guidance or regulations.

The electronic submission of NFDA's is part of CVM's ongoing initiative to provide a method for paperless submissions. This initiative reflects the principles behind the GPEA.

The GPEA of 1998 (Public Law 105–277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

Before submitting NFDA's by e-mail, sponsors should first register and follow the instructions in final guidance for industry (#108) entitled ''How to Use E–Mail to Submit Information to the Center for Veterinary Medicine.'' This final guidance is also available at http://www.fda.gov/cvm.

CVM monitors the final disposition of food animals treated with investigational new animal drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. Monitoring of the final disposition of such food animals is consistent with CVM's responsibility to protect the public health under the Federal Food, Drug, and Cosmetic Act. In addition, acceptable standards of study conduct such as those set out in 21 CFR 514.117 include sponsors accounting for the disposition of all animals treated with investigational new animal drugs. Furthermore, CVM requests this information because some animals are held for 30 days after the investigational drug withdrawal period ends, and CVM does not request a notice of intent to slaughter for human food purposes for these animals. Animals held for this period may still be sent for slaughter, however. CVM issues a slaughter authorization letter to sponsors that sets the terms under which animals treated with investigational new animal drugs may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit NFDA's for animals that are treated with investigational new animal drugs and are not intended for immediate slaughter. NFDA's have historically been submitted to CVM on