contains revisions incorporating many of those comments.

The PET CGMP guidance discusses the requirements for manufacturing practices, procedures, and facilities used to prepare PET radiopharmaceuticals. The guidance addresses such matters as quality control units, personnel qualifications, staffing, buildings and facilities, equipment, components, containers, closures, production and process controls, packaging and labeling controls, holding and distribution, testing and release for distribution, stability testing and expiration dating, reserve samples, yields, second-person checks, reports, and records. The guidance focuses particular attention on CGMP requirements that are of special concern due to unique characteristics inherent in the production and control of PET radiopharmaceuticals.

PET radiopharmaceutical drug product manufacturing differs in a number of important ways from the manufacture of conventional drug products:

(1) Because of the short physical half-lives of PET radiopharmaceuticals, PET facilities generally manufacture the products in response to daily demand for a relatively small number of patients.

(2) Manufacturing may be limited and only a few lots produced each day.

(3) PET radiopharmaceuticals must be administered to patients within a short period of time after manufacturing because of the short half-lives of the products.

FDA recognized that, because of these differences, application of certain provisions of the CGMP regulations in part 211 (21 CFR part 211) to the manufacture of PET radiopharmaceuticals might result in unsafe handling or be otherwise inappropriate. Therefore, elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule authorizing manufacturers of PET radiopharmaceuticals to apply to the agency for exceptions or alternatives to provisions of the CGMP regulations. The PET CGMP guidance notes that while the CGMP regulations apply to the manufacture of PET radiopharmaceuticals, new § 211.1(d) permits manufacturers of such drugs to request an exception or alternative to any requirement in part 211.

This guidance represents the agency's current thinking on CGMP's for PET radiopharmaceuticals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. A regulated entity may adopt an alternative approach to CGMP's for PET drugs if such approach satisfies the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. If written comments demonstrate that changes to the final guidance are appropriate, FDA will revise the guidance accordingly. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–10342 Filed 4–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. May 14, 1997, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 9, 1997, 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 required to make their comments.

Open committee discussion. The committee will hear presentations and discuss data submitted regarding new drug application 20–766, Xenical™ (orlistat, tetrahydrolipstatin, Hoffman-LaRoche, Inc.) for long-term treatment of obesity.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized,

however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10339 Filed 4–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form # HCFA–484; OMB # 0938–0534]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320 and public harm is likely to occur. The Oxygen Certificate of Medical Necessity, completed by a Medicare beneficiary's treating physician and a durable medical equipment supplier, must be submitted to the appropriate Medicare Durable Medical Equipment Regional Carrier before a Medicare beneficiary is deemed eligible for home oxygen therapy and before a durable medical equipment supplier is eligible for reimbursement. If emergency clearance is not provided, beneficiaries may be provided vital health services in an untimely manner or may be required to pay for oxygen services normally paid for by the Federal government.

HCFA is requesting that after the 30-day comment period has concluded, OMB complete its review within 7-days and provide a 180-day approval. During this 180-day period HCFA will publish a separate **Federal Register** notice announcing the initiation of a 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: Reinstatement of a collection with a change of a previously approved collection for which approval has expired (OMB approval # 0938–0534); *Title of Information Collection:* Attending Physician's Certification of Medical Necessity for Home Oxygen Therapy and Supporting Regulations 42 CFR 410.38 and 42 CFR 424.5; *Form Number:* HCFA–484; *Use:* To determine oxygen is reasonable and necessary pursuant to Medicare Statute, Medicare claims for home oxygen therapy must be supported by the treating physician's statement and other information including estimate length of need (# of months), diagnosis codes (ICD–9) and:

1. Results and date of the most recent arterial blood gas PO^2 and/or oxygen saturation tests.

2. The most recent arterial blood gas PO^2 and/or oxygen saturation test performed EITHER with the patient in a chronic stable state as an outpatient, OR within two days prior to discharge from an inpatient facility to home.

3. The most recent arterial blood gas PO_2 and/or oxygen saturation test performed at rest, during exercise, or during sleep.

4. Name and address of the physician/provider performing the most recent arterial blood gas PO_2 and/or oxygen saturation test.

5. If ordering portable oxygen, information regarding the patient's mobility within the home.

6. Identification of the highest oxygen flow rate (in liters per minute) prescribed.

7. If the prescribed liters per minute (LPM), as identified in item 6, are greater than 4 LPM, provide the results and date of the most recent arterial blood gas PO_2 and/or oxygen saturation test taken on 4 LPM.

If the PO_2=56–59, or the oxygen saturation=89%, then evidence of the beneficiary meeting at least one of the following criteria must be provided.

8. The patient having dependent edema due to congestive heart failure.

9. The patient having cor pulmonale or pulmonary hypertension, as documented by P pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement.

10. The patient having a hematocrit greater than 56%.

Form HCFA–484 obtains all pertinent information and promotes national consistency in coverage determinations; *Frequency:* Other (as needed); *Affected Public:* Individuals /households, business or other for profit, and not for profit institutions; *Number of Respondents:* 300,000; *Total Annual Responses:* 300,000; *Total Annual Hours Requested:* 50,000.

BILLING CODE 4120–03–P