results: Implications for the use of hormone therapy with estrogen/progestin, as a second-line drug, in the prevention and treatment of postmenopausal osteoporosis in women.

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 September 30, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 30, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Dornette Spell-LeSane at least 7 days in advance of the meeting.

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

Dated: September 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23334 Filed 9–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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: Circulatory System 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 October 2, 2003, from 9 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons C, D, and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. 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 an excimer laser and laser catheters used for treatment of chronic critical limb ischemia (associated with Rutherford Categories 4, 5, and 6). The device is intended for use in patients with angiographically evident culprit stenoses and/or occlusions in the superficial femoral artery, popliteal and/or infrapopliteal arteries, who are poor surgical candidates and who are acceptable candidates for revascularization. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*. Material will be posted on October 1, 2003.

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 September 22, 2003. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 22, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

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

Dated: September 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23331 Filed 9–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 4, 2003, (68 FR 45827). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, or e-mail: *patelA@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 4, 2003, FDA announced that a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee will be held on September 24 and 25, 2003. On page 45827, in the third column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On September 24, 2003, the committee will discuss new drug

application (NDA) 21–487, memantine hydrochloride, Forest Laboratories, Inc., indicated for the treatment of moderate to severe dementia of the Alzheimer's type. On September 25, 2003, the committee will discuss supplementary new drug application 20–717 /S–008 Provigil (modafinil) Tablets, Cephalon, Inc., indicated for use to improve wakefulness in patients with excessive sleepiness associated with disorders of sleep and wakefulness.

This notice is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 8, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23333 Filed 9–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0412]

International Conference on Harmonisation; Draft Guidance on E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides definitions associated with postapproval product safety information and standards for collecting and expedited reporting of safety information to the regulatory authorities. The draft guidance is intended to harmonize internationally the collection and management of postapproval product safety data.

DATES: Submit written or electronic comments on the draft guidance by October 20, 2003.

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Susan Lu, Center for Drug Evaluation and Research (HFD–430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1514; or Tim Cote, Center for Biologics Evaluation and Research (HFM–224), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6088.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0865.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: The European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research; FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In July 2003, the ICH Steering Committee agreed that a draft guidance entitled ''E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting'' should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft guidance will be considered by FDA and the Efficacy Expert Working Group.

In the **Federal Register** of March 1, 1995 (60 FR 11284), FDA published the ICH guidance entitled ''E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting,'' which provides guidance on preapproval safety data management. This ICH E2D draft guidance is based on the content of ICH E2A and provides further guidance on definitions associated with postapproval product safety information and standards for collecting and expedited reporting of safety information to the regulatory authorities.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be