

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations shall include complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

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

Dated: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 July 9, 2003, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Dornette Spell-LeSane, 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, e-mail: spelllesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21-366, CRESTOR (rosuvastatin calcium) tablets, AstraZeneca Pharmaceuticals LP, agent for iPR Pharmaceuticals, Inc., for the proposed indication of treatment of hypercholesterolemia and mixed dyslipidemia.

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 July 1, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 1, 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: May 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0203]

Innovative Systems for Delivery of Drugs and Biologics: Scientific, Clinical, and Regulatory Challenges Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss innovative systems for delivery of drugs and biologics. The purpose of this workshop is to serve as a forum for the academic and clinical communities, industry, consumer and patient advocacy groups, and FDA to discuss the latest scientific and clinical developments for these products, as well as any regulatory concerns and challenges. FDA hopes to facilitate the development of new technology by addressing and clarifying regulatory uncertainty and by increasing the predictability of product development. This project is a part of the Commissioner of the Food and Drug Administration's initiative entitled "Improving Innovation in Medical Technology: Beyond 2002." For reference, the white paper describing the entire initiative is available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00867.html>. The input received at the workshop and from written comments will be considered in drafting guidance or other information for industry.

Date and Time: The public workshop will be held on July 8, 2003, from 8 a.m. to 5:30 p.m.

Addresses: The public workshop will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814, 301-897-9400, FAX 301-897-0192. Submit written or electronic comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov. Additional information about the meeting and directions to the facility are available on the Internet at: <http://www.fda.gov/cdrh/meetings/070803.html>.

Contact Person: Cynthia Benson, Center for Devices and Radiological Health (HFZ-3), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-7989, e-mail: cmh@cdhr.fda.gov.