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.

[FR Doc. 03–14210 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. 03–14214 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

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@cdrh.fda.gov*.

Agenda: At the workshop, FDA will hear presentations and receive comments from stakeholders likely to be affected by FDA policies or procedures regarding the review and approval of innovative medical products. Stakeholders include, but are not limited to device, drug, and biological product manufacturers; members of the academic and clinical communities; and consumer and patient advocacy groups.

Registration: Preregistration is required by July 1, 2003, and will be accepted on a first-come, first-served basis; however, notwithstanding attendance at the workshop, interested persons are encouraged to provide comments (see the *Request for Comments* section of this document). There will be no onsite registration. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the public workshop. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/070803.html*. Persons without Internet access may call 1-888-203-6161. The registration deadline is July 1, 2003. For technical reasons, persons wishing to make an oral presentation at the public workshop must do so in person. Those who wish to make presentations should submit written notification including: (1) The specific issue related to the topic you intend to address; (2) the names and addresses of all individuals that will participate in your presentation; (3) the approximate amount of time your presentation will require; and (4) two copies of all presentation materials to Cynthia Benson by June 27, 2003. Presentations will be limited to the topics outlined in the **SUPPLEMENTARY INFORMATION** section of this document and, depending on the number of speakers, FDA may limit the time allotted for each presentation. If you need special accommodations due to a disability, please contact Anne Marie Williams at 301–594–1283 at least 7 days in advance.

Request for Comments: Regardless of attendance at the workshop, interested persons may submit written or electronic comments to the Dockets Management Branch (see the *Addresses* section of this document). You should annotate and organize your comments to identify the specific issues to which they refer. Submit two paper copies of any mailed comments. Individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The comments that FDA receives will be made available at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts: Following the workshop, transcripts will be available for review at the Dockets Management Branch (see the *Addresses* section of this document).

SUPPLEMENTARY INFORMATION: FDA believes that innovative and novel medical technologies have the potential to greatly improve the public health in many different areas. By addressing and clarifying regulatory uncertainty, the agency believes that the development of these technologies will be expedited and the predictability in product development will be increased, thus allowing more of these products to reach the marketplace in a timely manner. As part of a broad effort to increase the development of novel medical technologies, FDA is seeking information on how to expedite the review and approval of innovative devices for the delivery of drugs and biologics. For this effort, these products will be broadly defined. We are including any combination of drug and device or biologic and device products in which the two components work together to have a desired effect on the patient. Some examples of the innovative products to be included in this effort are:

- Novel, specialized catheters to permit localized delivery of drugs or biologics (*e.g.*, chemotherapeutic agents, thrombolytics, cells/biologics);
- Lasers or other energy delivery devices for delivery or enhancement of drug or biologic effectiveness (*e.g.*, electroporetic or laser systems to enhance the transport of drugs to the target site);
- Device/drug or device/biologic combinations that permit new routes of administration for drugs (*e.g.*, devices for inhalation of drugs formerly administered intravenously);
- Devices that activate drugs in the body (*e.g.*, photodynamic therapy);
- Drug-eluting stents designed to prevent restenosis; and
- Orthopedic repair products containing bone morphogenic proteins or other cytokines.

The lead for review of the products to be discussed in the workshop may be in any of the FDA medical products centers (the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health, *i.e.*, CDER, CBER or CDRH) and the products may reach the market through several different regulatory pathways (*e.g.*, investigational device exemption/premarket approval applications (IDE/PMA), investigational new drug application/new drug application (IND/NDA), IND/biological license application (BLA), IDE/510(k), or a combination of these). This workshop is being held to provide 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. In addition to increasing our understanding of the latest technological developments in this field, FDA is seeking input to specifically address the following:

1. What are the most critical challenges in developing and bringing to market a novel, innovative technology for delivery of drugs or biologics?
2. Which areas are most important for the agency to provide guidance to developers of these novel products?
3. How can the agency best collaborate with industry, academia, other government agencies, and other scientific bodies in this area of rapidly evolving technology?

The agency hopes to use the information from the workshop to guide the future development of guidance documents, memoranda of understanding, or other position papers.

Dated: May 27, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–14209 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0168]

Current Status of Useful Written Prescription Drug Information for Consumers: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers. Public Law 104–180 adopted a goal that useful written information would be distributed to 75 percent of individuals receiving new prescriptions by the year 2000. An FDA-commissioned study of