regarding IRB member conflicts of interest related to particular protocols.

Developing educational materials for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subjects research.

3. IRB Review

The Department recommends that IRBs reviewing HHS conducted or supported human subjects research or FDA regulated human subjects research consider whether the following actions, or other actions related to conduct or oversight of research, would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

Actions to consider:

Determining whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.

Determining whether other actions are necessary to minimize risks to subjects.

Determining the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

4. Investigators

The Department recommends that investigators conducting human subjects research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects, and what actions to take.

Actions to consider:

Including information in the informed consent document, such as

- The source of funding and funding arrangements for the conduct and review of research, or
- Information about a financial arrangement of an institution or an investigator and how it is being managed.

Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as

- Having a another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.
- Using independent monitoring of the research.

Dated: May 5, 2004.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 04–10849 Filed 5–11–04; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation 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: Orthopaedic and Rehabilitation 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 June 2, 2004, from 10 a.m. to 6 p.m. and June 3, 2004, from 8 a.m. to 5 p.m.

Location: Gaithersburg Marriott, Salons A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 2, 2004, the committee will discuss, make recommendations, and vote on a premarket approval application for an artificial lumbar disc intended for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L4–S1. On June 3, 2004, from 8 a.m. to 1 p.m., the committee will discuss, make recommendations, and vote on a reclassification petition for total and unicompartmental mobile bearing knee joint prostheses. Also on June 3, 2004, from 1 p.m. to 5 p.m., the committee will discuss and make recommendations on a draft guidance document for clinical performance data requirements for hip joint prostheses. The draft guidance document is available at *http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040504/03n-0561-c00001-vol2.pdf*. Background information for the topics, 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 for the June 2 session will be posted June 1, 2004. Material for the June 3 session will be posted June 2, 2004.

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 May 18, 2004. On June 2, 2004, 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. On June 3, 2004, oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. and 1:15 p.m. and 1:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 18, 2004, 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 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: May 3, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–10752 Filed 5–11–04; 8:45 am]

BILLING CODE 4160–01–S