(HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 20, 2001, the following committee updates are tentatively scheduled: (1) Transmissible spongiform encephalopathies guidance; hepatitis B surface antigen lot release guidance; human immunodeficiency virus (HIV) and hepatitis C virus nucleic acid testing; Clinical Laboratory Improvement Act waiver for HIV rapid tests; and (2) compliance quality control oversight. In the morning, the committee will hear presentations, discuss and make recommendations on potential concerns for simian foamy virus transmission by blood and blood products. In the afternoon, the committee will hear presentations, discuss and make recommendations on the leukocyte reduction guidance. On September 21, 2001, the committee will hear presentations, discuss and make recommendations on human cells, tissues and cellular and tissue-based products: risk factors for semen donation.

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 4, 2001. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m., and 3:45 p.m. and 4:45 p.m. on September 20, 2001; and between approximately 11:30 a.m. and 1 p.m. on September 21, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, 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.

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

Dated: August 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21361 Filed 8–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices Dispute Resolution 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: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting, which is rescheduled from June 4, 2001, will be held on September 6, 2001, from 8 a.m. to 6 p.m.

Location: Marriott, Salons E, F, and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact: Les Weinstein, Center for Devices and Radiological Health (HFZ–5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–6220, ext. 119, FAX 301–827–2565, lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and Lifecore Biomedical, Inc., related to the approvability of a premarket approval application for Intergel, an adhesion prevention solution for use in gynecologic pelvic surgery. Background information and questions for the committee will be available to the public on September 5, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

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 4, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on September 6, 2001. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the dispute before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes that there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: August 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21360 Filed 8–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is proposing to amend the provisions of the NIH Guidelines relating to the Recombinant DNA Advisory Committee (RAC) by authorizing a minimum of 15 voting members and establishing the charter of the committee as the controlling document for the membership and procedures of the RAC.

DATES: The public is encouraged to submit written comments on the