(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

proposed change. Comments may be submitted to the NIH Office of Biotechnology Activities (OBA) in paper or electronic form. Comments received on or before September 24, 2001 will be considered by NIH.

All comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892–7985, 301–496–9838, weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or want additional information about these proposed changes, please contact OBA by e-mail at *oba@od.nih.gov* or telephone at 301–496–9838. Comments should be addressed to the Dockets Manager and may be submitted to the same e-mail address, by fax to 301–496–9839, or by mail to the Office of Biotechnology Activities address above.

SUPPLEMENTARY INFORMATION

Section IV–C–2 of the NIH Guidelines provides that the RAC consists of 15 voting members including the Chair, appointed by the DHHS Secretary or designee, at least 8 of whom are selected from authorities knowledgeable in the fields of molecular genetics, molecular biology, recombinant DNA research, or other scientific fields. At least 4 members of RAC shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from designated Federal agencies serve as nonvoting members.

On January 23, 1997, the NIH Guidelines were amended to reduce the RAC from 25 to 15 voting members. This change was made in conjunction with the discontinuation of RAC's role in recommending approval or disapproval of individual gene transfer protocols. As stated in the November 22, 1996, Notice of Proposed Actions that included this reduction of RAC membership (61 FR 59725), the reduction was intended to ''increase efficiency while ensuring sufficient representation from scientific, ethical, and legal communities.'' Although RAC members no longer recommend approval or disapproval of gene transfer protocols, they review them to determine if they raise scientific, medical, safety, or ethical issues that require public discussion at a meeting of the RAC (see Appendix M and Appendix M–I–B–2 of the NIH Guidelines).

In the years since the number of RAC members was reduced, the number of gene transfer trials has dramatically increased, and those trials now encompass a broader array of clinical applications. Current trials address cancer, inborn errors of metabolism, cardiovascular diseases, autoimmune disorders, and neurologic diseases. In addition, current trials employ an increasing array of viral vectors, including vaccinia, fowl pox, canary pox, herpes simplex virus, adeno-associated virus, adenovirus, and retroviruses.

Thus, a broader range of expertise is needed on the RAC in order to adequately assess the issues raised by the many and increasingly varied proposed gene transfer trials submitted to the NIH. Given the dynamism of the field, flexibility in how this expertise is achieved is key to the effective and efficient functioning of the RAC. To this end, the NIH is proposing to amend Section IV–C–2 of the NIH Guidelines to authorize a minimum of 15 voting members with no maximum number of voting members specified. The maximum number of voting members will be established through the charter for the RAC, which is the controlling document for the membership and procedures of the RAC, in the event of any conflict with the NIH Guidelines. This will enable NIH to respond promptly to the need for additional expertise on the RAC through appropriate amendments to the charter.

Section IV–C–2 would also be amended to establish the RAC charter as the controlling document for the membership and functions of the RAC. In addition, the listing of specific types of knowledge for members who are not biomedical scientists would be broadened by changing ''applicable law'' to ''law,'' and ''standards of professional conduct and practice'' to ''ethics.''

Section IV–C–2 currently refers to the charter of the RAC, but it does not indicate that the charter sets forth the membership and procedures of the RAC, as well as its functions, or establish the charter as the controlling document in the event of a conflict with the NIH Guidelines. Under the proposed change, the NIH Guidelines would establish a minimum number of RAC members and the size of the RAC could vary according to need. The broad discretion of the Director, NIH, to choose members knowledgeable in certain fields would be retained, but the types of knowledge listed may periodically be changed.

Proposed Amendments to the NIH Guidelines

I. For the reasons stated above, it is proposed to amend Section IV-C–2 Recombinant DNA Advisory Committee (RAC) to state:

Section IV–C–2. Recombinant DNA Advisory Committee (RAC)

The RAC is responsible for carrying out the functions specified in the NIH Guidelines, as well as others specified in its charter or assigned by the Secretary of Health and Human Services or the NIH Director. The RAC membership and procedures, in addition to those set forth in the NIH Guidelines, are specified in the charter for the RAC, which is filed as provided in the General Services Administration Federal Advisory Committee Management regulations, 41 CFR Parts 101–6 and 102–3, and is available on the OBA website, http://www4.od.nih.gov/oba/rac/. In the event of a conflict between the NIH Guidelines and the charter, the charter shall control.

The RAC will consist of not less than 15 voting members, including the Chair, appointed under the procedures of the NIH and the Department of Health and Human Services. The maximum number and expertise of voting members will be established in the charter of the RAC. A majority of the voting members must be knowledgeable in relevant scientific fields, e.g., molecular genetics, molecular biology, recombinant DNA research, including clinical gene transfer research. At least 4 members of the RAC must be knowledgeable in fields such as public health, laboratory safety, occupational health, protection of human subjects of research, the environment, ethics, law, public attitudes or related fields. Representatives of the Federal agencies listed in the charter shall serve as nonvoting members. Nominations for RAC members may be submitted to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892–7985 (20817 for non-USPS mail), 301–496–9838, 301–496–9838 (fax).

All meetings of the RAC shall be announced in the **Federal Register**, including tentative agenda items, at least 15 calendar days before the meeting. Final agendas, if modified, shall be available at least 72 hours before the meeting. No item defined as a Major Action under Section IV–C–1–b–(1) may be added to an agenda following **Federal Register** publication.

OMB's ''Mandatory Information Requirement for Federal Assistance Program Announcements'' (45 FR 39592) requires a statement concerning the official Government programs contained in the Catalog of Federal

Domestic Assistance. Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the proposed guidance in this notice covers virtually every NIH and Federal research program in which recombinant DNA techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

Dated: August 16, 2001.

Ruth L. Kirschstein,

Acting Director, National Institutes of Health.

[FR Doc. 01–21392 Filed 8–23–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–62]

Notice of Submission of Proposed Information Collection to OMB; Compliance Inspection Report—HUD–92051 Mortgagee's Assurance of Completion—HUD–92300

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 24, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0189) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicalbe; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Compliance Inspection Report—HUD–92051; Mortgagee's Assurance of Completion—HUD–92300.

OMB Approval Number: 2502–0189.

Form Numbers: HUD–92051 and HUD–92300.

Description of the Need for the Information and Its Proposed Use: The Compliance Inspection Report (HUD–92051) is used by staff and private inspectors and appraisers. The Mortgagee's Assurance of Completion (HUD–92300) is used by mortgage companies for establishing escrow for incomplete repairs or construction. HUD staff review and approve these forms and use them in monitoring and training.

Respondents: Business or other for-profit.

Frequency of Submission: On occasion.

	Number of respondents	x	Frequency of response	x	Hours per response	=	Burden hours
Reporting Burden	14,500		251		0.25		909,875

Total Estimated Burden Hours: 909,875.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: August 17, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–21399 Filed 8–23–01; 8:45 am]

BILLING CODE 4210–72–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–320–1330–PB–24 1A]

Extension of Approved Information Collection, OMB Approval Number 1004–0169

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is requesting the Office of Management and Budget (OMB) to extend an existing approval to collect information from mining claimants concerning use and occupancy of their mining claims on public lands. BLM collects this information to analyze and approve proposed mining development activities on public lands. The nonform information under 43 CFR 3715 authorizes BLM to manage the use and occupancy on public lands for developing the mineral deposits by mining claimants.

DATES: You must submit your comments to BLM at the address below on or before October 23, 2001. BLM will not