DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on December 15–16, 1997. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on December 15, 1997, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will reconvene on December 16, 1997, at approximately 9:00 a.m. and will adjourn at approximately 5 p.m. The meeting will be open to the public to discuss Proposed Actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496) and other matters to be considered by the Committee. The Proposed Actions to be discussed will follow this notice of meeting. Attendance by the public will be limited to space available.

Debra W. Knorr, Acting Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone (301) 496–9838, FAX (301) 496–9839, will provide summaries of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Knorr in advance of the meeting.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) 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 guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. 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: October 7, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–27311 Filed 10–15–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research: Proposed Actions Under the 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: This notice sets forth proposed actions to be taken under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496, amended 59 FR 40170, 60 FR 20726, 61 FR 1482, 61 FR 10004, 62 FR 4782). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee (RAC) at its meeting on December 15–16, 1997. After consideration of these proposals and comments by the RAC, the NIH Director will issue decisions in accordance with the NIH Guidelines.

DATES: Interested parties are invited to submit comments concerning the proposed actions. Comments received by December 8, 1997, will be reproduced and distributed to the RAC for consideration at its December 15–16, 1997, meeting. After consideration of this proposal and comments by the RAC, the NIH Director will issue decisions in accordance with the NIH Guidelines.

ADDRESSES: Written comments and recommendations should be submitted to Debra Knorr, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839.

All comments received in response to this notice will be considered and will be available for public inspection in the above office on weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Background documentation and additional information can be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892–7010, Phone 301–496–9838, FAX 301–496–9839. The Office of Recombinant DNA Activities web site is located at http://www.nih.gov/od/orda for further information about the office.

I. Supplementary Information

The NIH will consider the following actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines):

I–A. Amendment to Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, Under the NIH Guidelines

During the June 12–13, 1997, RAC meeting, the following motions were approved by the Committee:

(1) A motion was made that Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, should be amended to require investigators to submit documentation verifying that a human gene transfer protocol has been submitted to an appropriate Institutional Biosafety Committee (IBC). Evidence of IBC notification shall be provided at the time the protocol is submitted to ORDA. The motion passed by a vote of 8 in favor, 1 opposed, and no abstentions.

(2) A motion was made to delete the requirement for submission of IBC and Institutional Review Board (IRB) approvals at the time of ORDA submission from Appendix M–I, Submission Requirements—Human Gene Transfer Experiments, of the NIH Guidelines. The motion passed by a vote of 7 in favor, 0 opposed, and 1 abstention.

On September 10, 1997, a letter was received from the American Biological Safety Association requesting that the public comment period for the proposed actions under the NIH Guidelines published in the **Federal Register** on August 20, 1997 (62 FR 44387) be extended for an additional 60 days.

During the September 12, 1997, RAC meeting, the RAC was scheduled to vote on the proposed actions to delete prior IBC and IRB approvals from the submission requirements, and to require investigators or sponsors to provide evidence of protocol submission to IBC.