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 June 8–9, 1995. The meeting will be held at the National Institutes of Health, Building 31C, 6th Floor, Conference Room 6, 9000 Rockville Pike, Bethesda, Maryland 20892, starting on June 8, 1995, at approximately 9 a.m., and will recess at approximately 6 p.m. The meeting will reconvene on June 9, 1995, at approximately 8:30 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. Members of the public wishing to speak at this meeting may be given such opportunity at the discretion of the Chair.

Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7052, 6006 Executive Boulevard, Suite 323, Bethesda, Maryland 20892–7052, Phone (301) 496–9838, FAX (301) 496–9839, will provide materials to be discussed at this meeting, roster of committee members, and substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Wivel in advance of the meeting. A summary of the meeting will be available at a later date.

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: May 15, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–12406 Filed 5–19–95; 8:45 am]

BILLING CODE 4140–01–M

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 (59 FR 34496).

SUMMARY: This notice sets forth proposed actions to be taken under the NIH Guidelines for Research Involving Recombinant DNA Molecules (59 FR 34496). Interested parties are invited to submit comments concerning these proposals. These proposals will be considered by the Recombinant DNA Advisory Committee at its meeting on June 8–9, 1995. After consideration of these proposals and comments by the Recombinant DNA Advisory Committee, the Director of the National Institutes of Health will issue decisions in accordance with the NIH Guidelines.

DATES: Comments received by June 1, 1995, will be reproduced and distributed to the Recombinant DNA Advisory Committee for consideration at its June 8–9, 1995, meeting.

ADDRESSES: Written comments and recommendations should be submitted to Dr. Nelson A. Wivel, Director, Office of Recombinant DNA Activities, National Institutes of Health, MSC 7052, 6006 Executive Boulevard, Suite 323, Bethesda, Maryland 20892–7052, or sent by FAX to 301–496–9839.

All comments received in timely 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 7052, 6006 Executive Boulevard, Suite 323, Bethesda, Maryland 20892–7052, Phone 301–496–9838, FAX to 301–496–9839.

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

I. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Drs. Curiel and Alvarez

In a letter dated January 5, 1995, Drs. David T. Curiel and Ronald D. Alvarez of the University of Alabama, Birmingham, Alabama, submitted a human gene transfer protocol entitled: A Phase I Study of Recombinant Adenovirus Vector-Mediated Delivery of an Anti-erbB–2 Single-Chain (sFv) Antibody Gene for Previously Treated Ovarian and Extraovarian Cancer Patients to the Recombinant DNA Advisory Committee for formal review and approval at its March 6–7, 1995, meeting. Due to reviewers' comments before the March 1995 meeting, the protocol was not forwarded to the committee.

In a letter dated April 12, 1995, Drs. David T. Curiel and Ronald D. Alvarez of the University of Alabama, Birmingham, Alabama, submitted a revised protocol to the Recombinant DNA Advisory Committee for formal review and approval at its June 8–9, 1995, meeting.

II. Addition to Appendix D of the NIH Guidelines Regarding a Human Gene Transfer Protocol/Dr. Curiel

In a letter dated April 13, 1994, Dr. David Curiel of the University of Alabama, Birmingham, Alabama, submitted the human gene transfer protocol entitled: Phase I Trial of a Polynucleotide Vaccine to Human Carcinoembryonic Antigen in Patients with Metastatic Colorectal Cancer to the Recombinant DNA Advisory Committee for formal review and approval at its June 9–10, 1994, meeting. During the June 1994 meeting, the committee approved the protocol by a vote of 10 in favor, 4 opposed, and no abstentions. Approval was contingent on the review and approval by the primary reviewers of a revised Informed Consent document (as approved by the Institutional Review Board). On June 29, Dr. Curiel submitted an Institutional Review Board approved Informed Consent Document. The primary reviewers approved the revised