

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Advisory Committee; Notice of Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Recombinant DNA Advisory Committee on March 11-12, 1999. 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 March 11, 1999, at approximately 9 a.m., and will recess at approximately 5 p.m. The meeting will reconvene on March 12, 1999, at approximately 8:30 a.m. and will adjourn at approximately 5 p.m. The meeting will be open to the public, except for a portion of the day on March 12. In accordance with sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., the meeting may be closed to the public on March 12 from approximately 10:00 a.m. to approximately 10:30 a.m. for the discussion of a protocol. These discussions could disclose trade secrets and commercial property such as patentable material and personal information concerning individuals associated with the protocols, the disclosure of which would constitute a clearly unwarranted invasion of privacy. The meeting will be held to discuss Proposed Actions 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, 62 FR 53335, 62 FR 56196, 62 FR 59032, 63 FR 8052, 63 FR 26018) and other matters to be considered by the Committee. The Proposed Actions 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 language interpretation or other reasonable accommodations, should contact Ms. Knorr in advance of the meeting. The Office of Recombinant DNA Activities (ORDA) web site is located at <http://www.nih.gov/od/orda> for further information about the office.

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 virtually every NIH and 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: February 8, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 99-3850 Filed 2-16-99; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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.

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, 62 FR 53335, 62 FR 56196, 62 FR 59032, 63 FR 8052, 63 FR 26018). 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 March 11-12, 1999. 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 this proposal. Comments received by February 24, 1999, will be reproduced and distributed to the RAC for consideration at its March 11-12, 1999, 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, or by FAX to 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 5:00 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' (ORDA) web site is located at <http://www.nih.gov/od/orda> for further information about the office.

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

I. Amendment to Appendix B-I. Risk Group 1 (RG1) Agents

On December 11, 1998, ORDA received a facsimile from Dr. Margarita C. Curras-Collazo, University of California at Riverside, Riverside, California, requesting under Section IV-C-1-(2), Minor Actions, of the NIH Guidelines, to lower the containment level (from Biological Level (BL) 2 to 1) for recombinant adeno-associated vectors (AAV) produced in the absence of helper viruses. Subsequent to this request, ORDA received a telephone call from Ms. Brenda Wong, Biological Safety Officer, University of California at San Diego, La Jolla, California, asking that this determination be reconsidered due to the potential of insertional metagenesis of recombinant AAV. ORDA has solicited the opinion of three experts in the AAV field, in addition to the opinion of the RAC Chair.

It is the opinion of the RAC Chair and the three experts that BL1 is appropriate for recombinant AAV vectors produced