

Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 24, 1996 (61 FR 50030), the agency announced that the proposed information collection had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), OMB has approved the information collection and assigned OMB control number 0910-0212. The approval expires on October 31, 1999. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: March 5, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-6361 Filed 3-12-97; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Institute of Mental Health; Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 17, 1997.

Time: 9:30 a.m.

Place: Parklawn, Room 9C-26, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Sheri L. Schwartzback, Parklawn, Room 9C-26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443-4843.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: March 25, 1997.

Time: 1 p.m.

Place: Parklawn, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857.

Contact Person: Jean K. Paddock, Parklawn, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301, 443-4868.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as

patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 97-6287 Filed 3-12-97; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

National Institute of Environmental Health Sciences; Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, Now Available

The publication Validation and Regulatory Acceptance of Toxicological Test Methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods, NIH Publication 97-3981 is now available and may be obtained as described in this notice.

Background

The National Institutes of Health Revitalization Act of 1993 (Pub. L. 103-43, Section 1301) directed the National Institute of Environmental Health Sciences of the National Institutes of Health (NIEHS/NIH) to "(a) establish criteria for the validation and regulatory acceptance of alternative testing methods, and (b) recommend a process through which scientifically validated alternative methods can be accepted for regulatory use" (Appendix F).

In response to these mandates, NIEHS established an ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (the Committee) in 1994 to develop a report recommending criteria and processes for validation and regulatory acceptance of toxicological testing methods that would be useful to Federal agencies and the scientific community. The following Federal regulatory and research agencies and organizations participated in this effort: Consumer Product Safety Commission, Department of Agriculture, Agriculture Research Service, Animal and Plant Health Inspection Service, Department of Defense, Department of Energy,

Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Food and Drug Administration, National Institute for Occupational Safety and Health/CDC, National Institute of Health, National Cancer Institute, National Institute of Environmental Health Sciences, National Library of Medicine, Office of Laboratory Animal Research, Department of the Interior, Department of Labor, Occupational Safety and Health Administration, Department of Transportation, Research and Special Programs Administration, Environmental Protection Agency.

The Committee met initially in September 1994, and then monthly or bimonthly until completion of the report in October 1996. The Committee interpreted its charge as the development of general criteria and processes for the validation and regulatory acceptance of new and revised toxicological test methods.

The specific goals of this Report are to:

- Communicate the criteria and procedures that Federal agencies should employ in considering new and revised test methods,
- Encourage the development of new and revised test methods that will provide for improved assessment of the potential toxicity of agents to human health and other organisms in the environment,
- Provide effective guidance for scientists for the validation and evaluation of new and revised test methods,
- Contribute to the increased likelihood of regulatory acceptance of scientifically valid new and revised test methods,
- Encourage the use of validated and accepted new and revised test methods,
- Encourage, when scientifically feasible, the reduction and refinement of animal use in testing and the replacement of animal methods with non-animal methods or of animal species with phylogenetically lower species.

In developing the initial draft report, the Committee considered information obtained from the following sources: (1) A questionnaire completed by each agency on their criteria and processes for test method validation and acceptance, (2) public comments submitted in response to a Federal Register notice published December 7,