

- 33–92 “Consistent Container Information in an Abbreviated Application” (This is addressed by MaPP 5225.2.)

- 34–92 “Implementation of the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Final Policy” (Revised October 3, 1992 (An agency-level policy addresses this topic.))

- 35–92 “Revision of Exhibit Batch Requirements for Abbreviated Antibiotic Drug Applications” (This became MaPP 5223.1; the MaPP was then withdrawn with repeal of section 507 of the act.)

- 36–92 “Submission of an Investigational New Drug Application to the Office of Generic Drugs” (This is addressed by MaPP 5240.4.)

- 37–92 “Management of Office and Center Committees” (This was previously withdrawn per memo dated February 14, 1997, because of center committee reorganization.)

- 38–93 “Restatement of the Office of Generic Drugs First In-First Reviewed Policy and Modifications of the Exceptions to the Policy Regarding Minor Amendments” (This is addressed by MaPP 5240.3.)

- 40–94 “Scoring Configuration of Generic Drug Products” (This is addressed by MaPP 5223.2.)

- 41–95 “Packaging of Test Batches” (This is addressed by MaPP 5225.1.)

A number of other PPGs and other OGD documents are undergoing revision. Some of them will be issued as MaPPs; others will be revised and reissued in the form of guidances for industry consistent with the GGP regulation.

The agency welcomes public comment on its efforts to review existing guidances related to the development of generic drugs and revise, reformat, or withdraw them as appropriate. The agency is also requesting public comment on topics for future guidance development regarding generic drugs.

This information is being issued consistent with FDA’s GGPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–26964 Filed 10–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee, Arthritis, Musculoskeletal, and Skin Diseases Committee.

Date: November 17–18, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Richard J. Bartlett, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 17, 2003.

Laverne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–26989 Filed 10–24–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of 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.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Pathology A Study Section.

Date: October 21–22, 2003.

Time: 7:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Terrace Hotel, 1515 Rhode Island Ave., NW., Washington, DC 20005.

Contact Person: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Genomics Shared Instruments.

Date: October 21, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2205, Bethesda, MD 20892, (301) 435–4511.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Pathophysiological Sciences Integrated Review Group, Alcohol and Toxicology Subcommittee 1.

Date: October 22–23, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Patricia Greenwel, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, (301) 435-1169, greenwel@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Oncological Sciences Integrated Review Group, Clinical Oncology Study Section.

Date: November 2-4, 2003.

Time: 5:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: John L. Meyer, PhD, Scientific Review Administrator, ONC IRG Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 435-1213, meyerjl@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cellular Mechanisms in Aging and Development Study Section.

Date: November 2-4, 2003.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: James P. Harwood, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7840, Bethesda, MD 20892, (301) 435-1256, harwoodj@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 301:RR03-002:Shared Instrumentation.

Date: November 3, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavillon, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Arthur A. Petrosian, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, (301) 435-1259, petrosia@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Discovery and Development of Therapeutics Study Section.

Date: November 3-4, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

Contact Person: Eduardo A. Montalvo, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SSS-B 02 M, Member Conflicts in Biophysics and Chemistry.

Date: November 3, 2003.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Donald Schneider, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172 MSC 7806, Bethesda, MD 20892, (301) 435-1727.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, SBIR Review Meeting.

Date: November 3, 2003.

Time: 8 a.m. to 12:01 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel—Downtown, 1250 22nd Street NW., Washington, DC 20037.

Contact Person: Mark P. Rubert, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218 MSC 7852, Bethesda, MD 20892, (301) 435-2398.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SSS-H (90) Computational Biology.

Date: November 3-4, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, 2401 M Street, NW., Washington, DC 20037.

Contact Person: George W. Chacko, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC: 7806, Bethesda, MD 20892, 301-435-1220, chackoge@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitation imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Chemistry/Biophysics SBIR/STTR Panel.

Date: November 3-4, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Vonda K. Smith, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172, MSC 7806, Bethesda, MD 20892, 301-435-1789, smithvo@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Digestive Sciences Integrated Review Group, Respiratory Physiology Study Section.

Date: November 3-4, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Governor's House Hotel, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Everett E. Sinnett, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1016, sinnett@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Brain Disorders and Clinical Neuroscience/BDCN/SBIR.

Date: November 3-4, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rene Etcheberrigaray, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, 301-435-1248, etcheber@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SSS-L(10)B Drug Delivery and Drug Discovery SBIR/STTR Panel.

Date: November 3-4, 2003.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Governor's House Hotel, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Sergei Ruvinov, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, (301) 435-1180, ruvinsr@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Alcohol and Toxicology Special Emphasis Panel.

Date: November 3, 2003.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham City Center, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Rass M. Shayiq, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-435-2359, shayiqr@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Behavioral Science Fellowship Review.

Date: November 3, 2003.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Michael Micklin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 435-1258, micklinm@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member conflicts: GMA-2 and GMA-3.

Date: November 3, 2003.

Time: 8:30 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Patricia Greenwell, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2175, MSC 7818, Bethesda, MD 20892, 301-435-1169, greenwep@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business Applications: Developmental Disabilities, Communication and Science Education.

Date: November 3-4, 2003.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Thomas A Tatham, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 594-6836, tathamt@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1 SSS-X 10B Small Business: Electromagnetics.

Date: November 3, 2003.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Rosslyn, 1900 North Fort Myer Drive, Arlington, VA 22209

Contact Person: Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171, rosenl@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, BSPH Member Conflict SEP.

Date: November 3, 2003.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel—Downtown, 1250 22nd Street, NW., Washington DC, DC 20037.

Contact Person: Mark P. Rubert, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218 MSC 7852, Bethesda, MD 20892, 301-435-2398, rubertm@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 NMB (04) Neurotoxicology of Heavy Metals.

Date: November 3, 2003.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Gamil C Debbas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435-1018, debbasg@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 40P: Program Project: Developing of Ultrasonic Tissue Characterization Methods.

Date: November 3-4, 2003.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Arthur A. Petrosian, PhD, Scientific Review Administrator, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, (301) 435-1259, petrosia@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 16, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-26988 Filed 10-24-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1473-DR]

American Samoa; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for American Samoa, (FEMA-1473-DR), dated June 6, 2003, and related determinations.

EFFECTIVE DATE: October 14, 2003.

FOR FURTHER INFORMATION CONTACT:

Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that special conditions are warranted regarding the cost-sharing arrangements concerning Federal funds provided under the authority of Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act). Therefore, consistent with the Insular Areas Act, 48 U.S.C. 1469a(d), and the President's declaration letter dated June 6, 2003, Federal funds for the Public Assistance and Hazard Mitigation Grant Programs, and for Other Needs Assistance under the Individuals and Households Program are authorized at 90 percent of total eligible costs for American Samoa. This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used