

that "A recall communication can be accomplished by telegrams, mailgrams, or first class letters * * *." Given the use of the term "can," we read the three examples as being illustrative rather than the sole means of accomplishing recall communications. Electronic notification is a viable alternative to more traditional methods.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on using electronic means to distribute certain product information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/oc/guidance/electronic.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 27, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-19731 Filed 9-28-05; 1:53 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 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 be constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Sickle Cell Disease Clinical Research Network.

Date: October 31–November 1, 2005.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: William J. Johnson, PhD, Review Branch, Division of Extramural Affairs, NIH/NHLBI, 6701 Rockledge Drive, Bethesda, MD 20892-7924, 301-435-0317, johnsonw@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 23, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-19537 Filed 9-29-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 discuss 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: National Heart, Lung, and Blood Institute Special Emphasis Panel, NHLBI Patient-Oriented K Applications.

Date: October 27–28, 2005.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Columbia Hotel, 10207 Wincopin Circle, Columbia, MD 21044.

Contact Person: Roy L. White, PhD, Scientific Review Administrator, Division of Extramural Affairs, Review Branch, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Rm. 7202, Bethesda, MD 20892-7924, 301/435-0310, whiterl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 23, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-19538 Filed 9-29-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of 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 open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552(b)(3)(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: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Kidney, Urologic and Hematologic Diseases D Subcommittee.

Date: October 18–19, 2005.

Open: October 18, 2005, 2 p.m. to 2:30 p.m.

Agenda: To review procedures and discuss policy.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: October 19, 2005, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Neal A. Musto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 751, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7798, muston@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Digestive Disease and Nutrition C Subcommittee.

Date: October 27-28, 2005.

Open: October 27, 2005, 8 a.m. to 8:30 a.m.

Agenda: To review procedures and discuss policy.

Place: Renaissance Hotel, 999 Ninth Street Northwest, Washington, DC 20001.

Closed: October 27, 2005, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Hotel, 999 Ninth Street Northwest, Washington, DC 20001.

Closed: October 28, 2005, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Hotel, 999 Ninth Street Northwest, Washington, DC 20001.

Contact Person: Paul A. Rushing, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, rushingp@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

Date: November 3-4, 2005.

Open: November 3, 2005, 6 p.m. to 6:30 p.m.

Agenda: To review procedures and discuss policy.

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

Closed: November 3, 2005, 6:30 p.m. to 11 p.m.

Agenda: To review and evaluate grant applications.

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

Closed: November 4, 2005, 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John F. Connaughton, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7797, connaughtonj@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology

and Hematology Research, National Institutes of Health, HHS)

Dated: September 21, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-19540 Filed 9-29-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Deafness and Other Communications Disorders Special Emphasis Panel, November 2, 2005, 8 a.m. to November 2, 2005, 5 p.m., Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on September 16, 2005, 70 FR 54759-54760.

The meeting will be held at the Bethesda Marriott Suites, 6711 Democracy Blvd., Bethesda, MD 20817, rather than at the Residence Inn Bethesda, as previously reported. The meeting is closed to the public.

Dated: September 22, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-19541 Filed 9-29-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Rodent Tissue Bank.

Date: October 13, 2005.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, 7201 Wisconsin Avenue, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7700, rv23r@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. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 22, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-19542 Filed 9-29-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Translational Research for the Prevention and Control of Diabetes.

Date: October 17, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Michelle L. Barnard, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy