The timely dissemination of communications about recalls of FDA regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We have encouraged manufacturers to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers to promote the use of electronic methods of communication and encourage the use of innovative technologies to disseminate safety information, particularly those that provide a public health benefit. We are making clear in the draft guidance that manufacturers may disseminate the communications discussed in §§ 7.49 and 200.5 (21 CFR 7.49 and 200.5) by e-mail or other electronic methods. The draft guidance also applies to those instances, not addressed in any regulation, where we recommend that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public.

The use of e-mail and other electronic communications has dramatically changed how we and the public convey information. Electronic communications have a number of advantages over paper-based communications. They can significantly shorten the time between an event and the public’s knowledge of the event. When the event involves product safety, it is even more important that accurate safety information be transmitted rapidly. E-mail and other electronic communications are generally considered more efficient and more timely than regular or traditional mail. These communications involve considerably less cost to the sender than older, more traditional delivery services. Verification of receipt or delivery is less expensive and can be automatically accomplished. Any necessary followup (such as when receipt of the e-mail is not acknowledged) also can be accomplished electronically. If receipt is never acknowledged, the sender can resort to more traditional methods of notification.

We interpret the provisions of §§ 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information. Section 7.49(b) provides...
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 FDA or the public. An alternative notification is a viable alternative to more traditional methods.

The draft guidance, when finalized, will be 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 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)


Anthony M. Coelho, Jr.,
Acting Director, Office of Federal Advisory Committee Policy.

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 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.


Date: October 18–19, 2005.

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

Agenda: To review procedures and discuss policy.