

B. Eligible Applicants

Assistance for this project will be provided only to the Save a Life Foundation. FY 2001 Federal appropriations specifically directs CDC to award funds to the Save a Life Foundation. No other applications are solicited.

Note: Title 2 of the United States Code, chapter 26, section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately \$810,000 is available in FY 2001 to fund one award. It is expected that the award will begin on or about September 1, 2001, and will be made for a 12-month budget period within a project period of one year. Funding estimates may change.

D. Where to Obtain Additional Information

For program technical assistance, contact:

Paul Burlack, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway N.E., Mailstop F42, Atlanta, GA 30341-3724, Telephone (770) 488-4713, Email: PBurlack@cdc.gov

To obtain business management technical assistance, contact:

Angelia Hill, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 01051, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Mailstop E13, Atlanta, GA 30341-4146, Telephone 770-488-2785, Email: aph8@cdc.gov

Dated: May 1, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01-11381 Filed 5-4-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Injury Research Grant Review Committee; Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease

Control and Prevention (CDC) announces the following committee meeting.

Name: Injury Research Grant Review Committee (IRGRC).

Times and Dates: 6:30 p.m.-9 p.m., May 20, 2001. 8 a.m.-5:30 p.m., May 21, 2001.

Place: The Westin Atlanta Airport, 4736 Best Road, College Park, Georgia 30337.

Status: Open: 6:30 p.m.-7 p.m., May 20, 2001. Closed: 7 p.m.-9 p.m., May 20, 2001, through 5:30 p.m., May 21, 2001.

Purpose: This committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the scientific merit and technical feasibility of grant applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focus on prevention and control and to support injury prevention research centers.

Matters To Be Discussed: Agenda items include a budget update, recent awards, future meeting dates, discussion of the review process and panelists responsibilities, and review of grant applications. Beginning at 7 p.m., May 20, through 5:30 p.m., May 21, the Committee will review individual research grant applications submitted in response to Program Announcements 01013, 01014, 01015, and 01016. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Deputy Director for Program Management, CDC, pursuant to Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Richard W. Sattin, M.D., Acting Executive Secretary, IRGRC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K58, Atlanta, Georgia 30341-3724, telephone 770/488-4330.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 25, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01-11378 Filed 5-4-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****National Vaccine Advisory Committee, Subcommittee on Vaccine Safety and Communication Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following Federal advisory Subcommittee meeting.

NAME: National Vaccine Advisory Committee (NVAC) Subcommittee on Vaccine Safety and Communications.

TIME AND DATE: 2 p.m.—5 p.m., June 5, 2001.

PLACE: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW, Washington, DC 20201.

STATUS: Open to the public, limited only by the space available.

NOTICE: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building between 12:30 p.m. and 1 p.m. Entrance to the meeting at other times during the day cannot be assured.

STATUS: Open to the public, limited only by the space available.

PURPOSE: This Subcommittee reviews issues relevant to vaccine safety and adverse reactions to vaccines.

MATTERS TO BE DISCUSSED: Review of the agenda; review of National Infant Immunization Week; discussion on strengthening the vaccine supply; follow-up to the "Workshop on Vaccine Communications"; review of the Institute of Medicine's (IOM) report on Measles-Mumps-Rubella Vaccine and Autism, discussion of the process for suggesting and selecting immunization safety issues for review by the IOM in 2002; public comment on immunization safety issues for review in 2002; and committee discussion.

Special Note: The Subcommittee on Vaccine Safety and Communications will provide a forum for input from the public regarding potential issues and topics for

review in 2002 by the IOM's Immunization Safety Review Committee. This will be the first opportunity for the public to provide comments on the hypotheses that are being considered for future review.

Agenda items are subject to change as priorities dictate. A complete meeting agenda of the Subcommittee on Vaccine Safety and Communications can be found on the National Vaccine Program Office's web site at www.cdc.gov/od/nvpo/calendar.

CONTACT PERSON FOR MORE INFORMATION: Ms. Shaunette Crawford, Associate Director for Health Communications and Legislation, NVPO, CDC, 1600 Clifton Road, NE, M/S D-66, Atlanta, Georgia 30333, telephone 404/687-6672.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 1, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01-11371 Filed 5-4-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 005

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication entitled "Modifications to the List of Recognized Standards, Recognition List Number: 005" (Recognition List Number: 005) will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written comments concerning this document at any time. See section VI of this document for the

effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of "Modification to the List of Recognized Standards, Recognition List Number: 005," to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. Submit written comments concerning this document to the contact person (address below). Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed on FDA's Internet site at <http://www.fda.gov/cdrh/fedregin.html>. See section V of this document for electronic access to the searchable database for the current list of "FDA Recognized Consensus Standards," including Recognition List Number: 005 modifications, and other standards related information.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: Carol L. Herman, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4766, ext. 156.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of the guidance entitled "Recognition and Use of Consensus Standards." This notice described how FDA will implement its standards program recognizing the use of certain standards and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), and November 15, 2000 (65 FR 69022), FDA modified its initial list of recognized standards.

These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. When these notices were published, the agency maintained "html" and "pdf" versions of the list of "FDA Recognized Consensus Standards." Both versions were publicly accessible at the agency's Internet site. The agency maintains the current list in a searchable database accessible to the public. See section V of this document for electronic access information.

II. Discussion of Modifications to the List of Recognized Standards, Recognition List Number: 005

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews for devices. FDA will incorporate these modifications in the list of "FDA Recognized Consensus Standards" in the agency's searchable database. FDA will use the term "Recognition List Number: 005" to identify: (1) Supplementary information sheets for standards added to the list for the first time, (2) standards added to replace withdrawn standards, and (3) still recognized standards for which minor revisions are made to clarify the application of the standards.

At the end of this notice, FDA lists modifications the agency is making that involve: (1) The initial addition of standards not previously recognized by FDA and (2) the addition of standards in conjunction with the withdrawal of other standards that are replaced by these later, amended, or different standards.

In this section, FDA describes modifications that involve the withdrawal of standards and their replacement by others. In this notice, all changes of this type are in the sterility category of the complete list of recognized standards.

1. ASTM-F1140:1996 is withdrawn under previous item 59. ASTM-F1140:2000 is added under current item 67.

2. ASTM-F1585:1995 is withdrawn under previous item 61. ASTM F1585:2000 is added under current item 68.

3. ASTM-1608:1995 is withdrawn under previous item 62. ASTM F1608:2000 is added under current item 69.

III. List of Recognized Standards

FDA maintains the agency's current list of "FDA Recognized Consensus Standards" in a searchable database that may be accessed directly at FDA's Intranet site at <http://>