VerDate Jan<31>2003 16:38 Sep 04, 2003 Jkt 200001 PO 00000 Frm 00048 Fmt 4703 Sfmt 4703 E:\FR\FM\05SEN1.SGM 05SEN1

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persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance.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 to http://www.fda.gov/dockets/ecomments or two copies of any mailed comments, except that individuals may submit one copy. The draft guidance and the comments submitted to the docket may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/dockets/default.htm.


Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–22576 Filed 9–03; 10:00 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Developing Compliance Program Guidance for Recipients of NIH Research Grants

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice seeks the input and recommendations of interested parties as the OIG develops compliance program guidance (CPG) for recipients of extramural research grant and cooperative agreement (grant) awards from the National Institutes of Health (NIH). The OIG is soliciting comments, recommendations and other suggestions from interested parties and organizations on the value and fundamental principles of compliance programs for colleges, universities, and other recipients of NIH grants, along with the specific elements that these grant recipients should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on November 4, 2003.

ADDRESSES: Please mail or deliver your written comments, recommendations and suggestions to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG–13–CPG, Room 5527, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG–13–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5527 of the Cohen Building at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

1. Past CPGs

The development of compliance program guidance is a major initiative of the OIG in its effort to assist participants in Department programs in preventing and reducing fraud and abuse and in better complying with Federal program requirements. Over the past several years, the OIG has developed and issued 11 compliance program guidelines. The suggestions contained in the guidances are not mandatory, nor do they represent an exclusive discussion of the advisable elements of a compliance program.

2. Developing Draft CPG for NIH Research Grant Recipients

Through this Federal Register notice, the OIG is seeking input from interested parties as the OIG considers the development of a CPG for recipients of extramural research grant awards from NIH. Under its governing statute, the OIG’s oversight responsibility extends to all programs and operations of the Department, and the OIG promotes compliance efforts by all recipients of Department funds. One community of paramount importance to the Government’s public health efforts is the colleges, universities, and other recipients of public funds committed to furthering biomedical research. These organizations are largely non-profit and educational, with over 50 percent of recipients of NIH research grant awards in the last several years being medical schools. Many of these organizations have instituted health care compliance programs in their hospitals, and an increasing number have begun developing compliance programs for sponsored research.

As with OIG’s earlier CPGs, the purpose of this guidance will be to assist organizations in preventing fraud and abuse and in better complying with Federal requirements. We anticipate that the guidance for recipients of NIH research grants will contain seven elements that we consider necessary for a comprehensive compliance program. These seven elements include:

• Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance;
• Designating a compliance officer and compliance committee;
• Conducting effective training and education;
• Developing effective lines of communication;
• Conducting internal monitoring and auditing;
• Enforcing standards through well-publicized disciplinary guidelines; and
• Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate Federal agency.

We are also considering an eighth element, “Defining roles and responsibilities and assigning oversight responsibility,” that would include a discussion of the importance of effectively delegating oversight authority.

We would appreciate specific comments, recommendations and suggestions on aspects of these elements.

We are also interested in comments on (a) the scope of the guidance, and particularly the types of activities, such as grant administration, that should be subject to the CPG; and (b) the risk areas for recipients of NIH research grants. Based on our fraud investigations at research institutions, we have identified internal control deficiencies that may warrant attention in a CPG. OIG would also appreciate suggestions from the public on risk areas. Risk areas we have tentatively identified include: (i) The proper allocation of charges to grant projects; (ii) “time and effort” reporting, including an accurate reporting of the commitment of effort by researchers; and (iii) use of program income. We would also be interested in comments on each of these areas.

We will consider all comments, recommendations and suggestions received within the time frame...
DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Aviation Security Advisory Committee Meeting

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Aviation Security Advisory Committee (ASAC).

DATE: The meeting will take place on October 1, 2003, from 9 a.m. to 1 p.m.

ADDRESS: The meeting will be held at the Crowne Plaza Washington National Hotel, 1489 Jefferson Davis Highway, Arlington, VA 22202. Telephone: (703) 416–1600.

FOR FURTHER INFORMATION CONTACT: Joseph Corrao, Office of Transportation Security Policy, TSA Headquarters (Room 1146N), 701 S. 12th Street, Arlington, VA 22202; telephone 571–227–2980, e-mail joseph.corrao@dhs.gov.

SUPPLEMENTARY INFORMATION: This meeting is announced pursuant to section 10(a)(2) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.). The agenda for the meeting will include the report of the air cargo transportation security working groups, and the report of the general aviation airport security guidelines working group. This meeting, from 9 a.m. to 1 p.m., is open to the public but attendance is limited to space available.

Members of the public must make advance arrangements to present oral statements at the open ASAC meeting. Written statements may be presented to the committee by providing copies of them to the Chair prior to or at the meeting. Anyone in need of assistance or a reasonable accommodation for the meeting, should contact the person listed under the heading FOR FURTHER INFORMATION CONTACT. In addition, sign and oral interpretation, as well as a listening device, can be made available at the meeting if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading FOR FURTHER INFORMATION CONTACT.

Issued in Arlington, Virginia, on September 2, 2003.

Tom Blank, Assistant Administrator for Transportation Security Policy.

BILLING CODE 4160–84–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Property Suitable as Facilities To Assist the Homeless

[DOCKET NO. FR–4809–N–36]

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.


FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 789–1234; TTY number for the hearing- and speech-impaired (202) 789–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in National Coalition for the Homeless v. Veterans Administration, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today’s Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.


Mark R. Johnston, Deputy Director, Office of Special Needs Assistance Programs.

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Wildlife and Plants; 90-Day Finding on Petition To Delist Astragalus magdalenaev var. peirsonii (Peirson’s milk-vetch)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 90-day petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service, make a 90-day finding for a petition to remove Astragalus magdalenaev var. peirsonii (Peirson’s milk-vetch) from the Federal List of Threatened and Endangered Wildlife and Plants pursuant to the Endangered Species Act (ESA) (16 U.S.C. 1531 et seq.). We find that the petition presents substantial information indicating that delisting this plant may be warranted. We are initiating a status review to determine if delisting this species is warranted.

DATES: This finding was made on August 29, 2003. To be considered in the 12-month finding on this petition, comments and information should be submitted to us by November 4, 2003.

ADDRESS: Comments, material, information, or questions concerning this petition and finding should be sent to the Field Supervisor, Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 6010 Hidden Valley Road, Carlsbad, CA 92009. The petition and supporting information are available for public inspection by appointment during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Jim Bartel, Field Supervisor, Carlsbad Fish and Wildlife Office, at the above address (telephone: 760–431–9440).

SUPPLEMENTARY INFORMATION: Background

Section 4(b)(3)(A) of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531 et seq.) requires that we make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating that the petitioned action may be warranted. To the maximum extent practicable, this finding is to be made within 90 days of receipt of the petition, and the finding is to be published promptly in the Federal Register. If we find substantial information present, we are required to promptly commence a review of the status of the species (50 CFR 424.14). “Substantial information” is defined in 50 CFR 424.14(b) as “that amount of...”