ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled “Guidance Levels for Radionuclides in Domestic and Imported Foods.” The draft CPG would rescind and replace the current CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14). The draft CPG provides updated guidance levels for radionuclide activity concentration in food offered for import and makes these same guidance levels for radionuclide activity concentration applicable to food in domestic interstate commerce for the first time. The draft CPG also expands the scope of coverage of FDA policy from food accidentally contaminated with radionuclides to food accidentally or intentionally contaminated with radionuclides. The agency is also announcing the availability of a draft supporting document entitled “Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods.”

DATES: Submit written or electronic comments concerning the draft CPG and/or the draft supporting document by March 15, 2004.

ADDRESSES: Submit written requests for single copies of the draft CPG entitled “Guidance Levels for Radionuclides in Domestic and Imported Foods” and/or the draft supporting document entitled “Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods” to Paul South (see FOR FURTHER INFORMATION CONTACT). Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to this document. Submit written comments on the draft CPG and/or draft supporting document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecoments.

FOR FURTHER INFORMATION CONTACT: Paul South, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1640, fax: 301–436–2651, e-mail: psouth@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a draft CPG to rescind and replace CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14) concerning radionuclides in food. While CPG Sec. 560.750 Radionuclides in Imported Foods—Levels of Concern (CPG 7119.14), which was issued in 1986 following the Chernobyl nuclear accident, only addresses radionuclides in food offered for import, this draft CPG is intended to provide clear policy and regulatory guidance to FDA’s field and headquarters staff with regard to radionuclides in both food offered for import and domestic food in interstate commerce. In particular, the draft CPG sets forth new guidance levels for radionuclides, referred to as Derived Intervention Levels (DILs). FDA would use DILs to help determine whether food in interstate commerce or food offered for import into the United States presents a safety concern. The DILs adopted in the draft CPG are not binding on FDA, the regulated industry, or the courts. In any given case, FDA may decide to initiate an enforcement action against food with concentrations below the DILs or decide not to initiate an enforcement action against food with concentrations that meet or exceed the DILs. The scientific basis for the DILs established in the draft CPG is presented in the draft supporting document. The draft CPG also contains information that may be useful to the regulated industry and to the public.

The agency has adopted good guidance practices (GGPs) that set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (21 CFR § 10.115). The draft CPG is being issued as a Level 1 draft guidance consistent with GGPs. The draft CPG represents the agency’s current thinking on its enforcement process concerning the adulteration of foods with radionuclides. It does not create or confer any rights for or on any person and does not operate to bind FDA, or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the draft CPG and the draft supporting document. 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. Received comments, the draft CPG, and the draft supporting document 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 CPG and the draft supporting document at http://www.fda.gov/ora under “Compliance References.”


John M. Taylor,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–719 Filed 1–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Agency Information Collection Activities (OIG–319–FN)

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

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this notice sets forth the Office of Inspector General’s summary of collection activities with regard to State Medicaid Fraud Control Units’ Recertification Application and Annual Reports, as required by 42 CFR 1007.15 and 1007.17 of the OIG regulations. A proposed notice of these information collection activities was published for public comment in the March 26, 2003 edition of the Federal Register (68 FR 14668). No public comments were received in response to that proposed collection activities notice.

SUPPLEMENTARY INFORMATION: Type of Information Collection Request: Reinstatement of an expired collection.

Title of Information Collection: State Medicaid Fraud Control Units’ Recertification Application and Annual Report as required by 42 CFR 1007.15 and 1007.17. (Previously approved by the Office of Management and Budget under control number 0990–0162.)

Use: The information contained in the annual reports and recertification application is required for certification and yearly recertification by the OIG to ensure that federal matching funds are only expended for allowable costs, and to determine if a State unit needs technical assistance.

Frequency: Annually.

Affected Public: State government.

Annual Number of Respondents: 48.

Total Annual Responses: 48.

Average Burden Per Response: 32 hours.

Total Annual Hours: 2,744 hours.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 Cancer Institute Special Emphasis Panel, Development/Pilot Projects in Cancer Complementary and Alternative Medicine (CAM).

Date: March 8–10, 2004.

Time: 7 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

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

Contact Person: Gerald G. Lowinger, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8101, Rockville, MD 20822–7405, 301/496–7987.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)


LaVerne Y. Stringfield, Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–742 Filed 1–13–04; 8:45 am] BILING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Dermatomyositis Clinical Trial Applications.

Date: January 26, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Aftab A. Ansari, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Boulevard, Bldg. 1, Ste. 800, Bethesda, MD 20892, (301) 594–4974, nuckolls@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.364, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)


LaVerne Y. Stringfield, Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–737 Filed 1–13–04; 8:45 am] BILING CODE 4140–01–M