should read: Interested manufacturers should submit a letter of interest with information about their capabilities to the following e-mail address: *esli@cdc.gov.*

On page 48499 under the heading **FOR FURTHER INFORMATION CONTACT** change to read: *esli@cdc.gov.*

Dated: August 25, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–19931 Filed 8–31–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD–9–CM Coordination and Maintenance Committee meeting.

Times and Dates: 9 a.m.–4 p.m., October 7–8, 2004.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD–9–CM Coordination and Maintenance (C&M) Committee will hold its final meeting of the 2004 calendar year cycle on Thursday and Friday, October 7–8, 2004. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters To Be Discussed: Agenda items include:

Diabetic peripheral neuropathy, diabetic retinopathy and diabetic macular edema.

Renal failure, continued.

At-risk for perioperative myocardial ischemia.

Mechanical complication of joint prosthesis.

Metabolic disorders.

Refractory anemia.

Insomnia and hypersomnia.

ICD–10–Procedure Classification System (PCS)—Update.

Revision of hip replacement.

Revision of knee replacement.

Sublingual Capnometry.

Implantation of prosthetic cardiac support device.

Multiple vessel drug-eluting stent.

Revision of CRT–D pocket.

Insertion of rechargeable neurostimulator pulse generator.

Infusion of liquid radioisotope for treatment of malignant brain tumor.

Addenda.

Contact Person for Additional Information: Amy Blum, Medical Classification Specialist, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone 301–458–4106 (diagnosis), Amy Gruber, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Blvd., Room C4–07–07, Baltimore, Maryland, 21244, telephone 410–786–1542 (procedures).

Notice: In the interest of security, CMS has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Because of increased security requirements, those who wish to attend a specific ICD–9–CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the October 7–8, 2004 meeting must submit their name and organization by October 4, 2004 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD–9–CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend.

Send your name and organization to one of the following by October 4, 2004 in order to attend the October 7–8, 2004 meeting: Pat Brooks, *pbrooks1@cms.hhs.gov*, 410–786–5318. Ann Fagan, *afagan@cms.hhs.gov*, 410–786–5662. Amy Gruber, *agruber@cms.hhs.gov*, 410–786–1542.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 25, 2004.

Alvin Hall,

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

[FR Doc. 04–19945 Filed 8–31–04; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0455]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). This training program was initiated in 1999, and it is intended to give CDER regulatory project managers an opportunity to tour pharmaceutical facilities and to exchange regulatory experiences with their industry counterparts. The Site Tours Program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. Further, this program is intended to improve communication and cooperation between CDER staff and industry. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by November 1, 2004.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Office of New Drugs (HFD–020), Center for Drug Evaluation and Research, Food and Drug Administration, 5515 Security Lane, rm. 7219, Rockville, MD 20852, 301–594–3937, FAX: 301–480–8329.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, the center has initiated various training and development programs to promote high performance

in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing this training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

Firms interested in offering a site tour or learning more about this training opportunity should respond within 60 days of this notice by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION CONTACT**).

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19879 Filed 8–31–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Information Collection: Request for Public Comment: 30-Day Notice

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day proposed information collection: IHS Urban Indian Health Program Common Reporting Requirements.

SUMMARY: The Indian Health Service, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collection of information in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval. The IHS received no comments in response to the 60-day **Federal Register** notice (FR 04–8721) published on 4/19/04. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

Proposed Collection

Title: 0917–0007, ''IHS Urban Indian Health Program Common Reporting Requirements.''

Type of Information Collection Request: Extension of a currently approved information collection.

Form Number: The report formats are contained in IHS instruction manual, ''Urban Indian Health Programs Common Reporting Requirements.'' The reporting formats have been computerized for electronic data submission.

Need and Use of Information Collection: IHS contracts with urban Indian organizations to: access and identify health services available to urban Indians; provide health education and health services to urban Indians; identify the unmet health needs of urban Indians; and, make recommendations on methods to improve health services provided to urban Indians. The information is collected annually and used to: monitor contractor performance; prepare budget reports; allocate resources; and, access and evaluate the urban Indian health contract programs.

Affected Public: Individuals or households, not-for-profit institutions, and State, Local or Tribal Government.

Type of Respondents: Urban Indian Health care organizations.

The table below provides the following: types of data collection instruments, estimated number of respondents, number of responses per respondent, annual number of responses, average burden hours per response, and total annual burden hours.

Data collection instruments	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hrs per response*	Total annual burden hrs
Face Sheet	34	1	34	0.50 (30 mins)	17.0
Table 1	34	1	34	2.00 (120 mins)	68.0
Table 2	34	1	34	0.75 (45 mins)	25.5
Table 3	34	1	34	2.25 (135 mins)	76.5
Table 3A	34	1	34	1.05 (65 mins)	36.0
Table 3B	34	1	34	0.25 (15 mins)	8.5
Table 3C	34	1	34	0.33 (20 mins)	11.0
Table 3D	34	1	34	1.25 (75 mins)	42.5
Table 4	(**)	1		0.50 (30 mins)	17.0