H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Semi-annual progress reports should include:

a. A brief project description

b. A comparison of the actual accomplishments to the goals and objectives established for the period

c. In the case that established goals and objectives may not be accomplished or are delayed, documentation of both the reason for the deviation and the anticipated corrective action or a request for deletion of the activity from the project

d. Other pertinent information, including preliminary findings from the analysis of available data

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a), 311, and 317 of the Public Health Service Act, [42 U.S.C. sections 241, 243, and 247b4], as amended. The Catalog of Federal Domestic Assistance number is 93.184.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Program Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sheryl Heard, Grants Management Specialist, Assistance and Acquisition Branch B, Procurement and Grants Office, Centers for Disease Control and Prevention.

[Announcement 02026]

2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146. *Telephone number:* 770–488–2723. *E-mail: slh3@cdc.gov.*

For program technical assistance, contact: Tom Horne, National Center on Birth Defects and Developmental Disabilities. 4770 Buford Highway, Mail Stop F–15 Atlanta, Georgia 30341. *Telephone number:* 770–488–7364. *E-mail:* tjh1@cdc.gov.

Robert L. Williams,

Chief, Assistance and Acquisition Branch B., Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02–2941 Filed 2–6–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Hearing Sensitivity and Exposure to Noise and/or Chemicals, RFA OH–02–003.

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 meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Hearing Sensitivity and Exposure to Noise and/or Chemicals, RFA OH–02–003.

Times and Dates: 8 a.m.–8:30 a.m., March 14, 2002 (Open) 8:30 a.m.–5 p.m., March 14, 2002 (Closed)

Place: Hilton Old Town, 1767 King Street, Alexandria, Virginia 22314.

Status: Portions 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.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA OH–02–003.

Contact Person for More Information: Price Connor, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE, M/S E20, telephone (404) 498–2511.

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: January 30, 2002.

Alvin Hall,

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

[FR Doc. 02–2942 Filed 2–6–02; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC): Meeting

ACTION: Location Change.

SUMMARY: Department of Health and Human Services, Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee published a document in the **Federal Register**.

Federal Register: January 22, 2002 (Volume 67, Number 14) (Page 2889–2890).

Name: Healthcare Infection Control Practices Advisory Committee.

Times and Dates: 8:30 a.m.–5 p.m., February 25, 2002, 8:30 a.m.–4 p.m., February 26, 2002.

Correction

Old Location: Radisson Buckhead/Emory Area Inn, 2061 North Druid Hills Road, Atlanta, Georgia 30329.

New Location: Atlanta Century Center Marriott, Meeting Room: Century West, 2000 Century Boulevard NE, Atlanta, Georgia 30345 Phone: 404–348–1110.

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

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Michele L. Pearson, M.D., Executive Secretary, HICPAC, Division of Healthcare Quality Promotion, NCID, CDC, 1600 Clifton Road, NE., M/S A07, Atlanta, Georgia 30333, telephone 404/498–1182.

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: January 31, 2002.

Alvin Hall,

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

[FR Doc. 02–2940 Filed 2–6–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0007]

Agency Information Collection Activities; Proposed Collection; Comment Request; CGMP Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

DATES: Submit written or electronic comments on the collection of information by April 8, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

CGMP Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control No. 0910–0139)—Extension

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the CGMP to ensure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

FDA has the authority under section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over-the-counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that ''for records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.'' To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated