

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 97-1233 Filed 1-16-97; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH); 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: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Time and Date: 8 a.m.-5 p.m., February 4-5, 1997.

Place: Terrace Garden Hotel, Magnolia Room, Terrace Meeting Level Access, 3405 Lenox Road, NE, Atlanta, Georgia 30326.

Status: The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Purpose: The Safety and Occupational Health Study Section will review, discuss and evaluate grant applications in response to NIOSH's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation of the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness.

Research funded will examine and evaluate current and emerging problems in occupational safety and health in a variety of settings for health and injured workers.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285-5979.

Dated: January 13, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97-1208 Filed 1-16-97; 8:45 am]

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Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part 60 FR 53379, October 13, 1995) is amended to reflect an organizational change in the Office of Testing and Research and the Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), in the Food and Drug Administration (FDA).

CDER believes this organizational change will improve operations management and strengthen the existing research and testing structure to more effectively accomplish the Center's mission.

Under section HF-B, Organization:

1. Delete the subparagraphs under the Chemistry Policy Staff (HFNS1), Office of Pharmaceutical Science and insert the following new subparagraphs under Product Quality Support Staff (HFNS1), reading as follows:

Product Quality Support Staff (HFNS1). Manages and facilitates the development, review, coordination, dissemination, organization, and implementation of new chemistry manufacturing policies, procedures, and guidelines related to chemistry and microbiology reviews of new and generic drug applications.

Performs assessments of environmental impact of actions within the drug approval system which may significantly affect the quality of the human environment.

Performs quality assurance and quality control functions for chemistry reviews of both new and generic drug applications.

Provides support for the operations of quality expert working groups or committees focused on the chemistry

manufacturing control technical aspects of the drug review process.

Provides necessary training for chemists, as appropriate.

Develops and implements policies and procedures in support of compendial operations and directs appropriate programs related to compendial initiatives.

2. Delete the subparagraphs under the Formulation Research Staff (HFNS2), Office of Pharmaceutical Science (HFNS) in its entirety.

3. Delete the subparagraphs under the Office Testing and Research (HFNSD) in its entirety and insert new subparagraphs reading as follows:

Office of Testing and Research (HFNSD). Conducts research and develops scientific standards on the composition, quality, safety, and effectiveness of human drug products.

Directs the FDA insulin certification program.

Directs large scale drug quality surveillance activities for the Center as required by regulations.

Conducts and coordinates basic and applied research.

Provides scientific training for new employees through the development and coordination of Staff College programs.

Sponsors cooperative university-based and industry-linked education programs for postdoctoral traineeships and sabbatical programs. Initiates and coordinates the holding of scientific workshops.

In coordination with the Office of the Commissioner, educates the public on Center and Agency policy and activities.

4. Insert the following new subparagraphs under the Regulatory Research and Analysis Staff (HFNSD-1), Office of Testing and Research (HFNSD) reading as follows:

Regulatory Research and Analysis Staff (HFNSD-1). Serves as the scientific and regulatory liaison to the FDA National Center for Toxicological Research, the National Institute of Environmental Health Sciences National Toxicology Program and other Federal agencies. Coordinates Center-sponsored and Center-related research and communicates scientific information to the Office of Review Management, the Pharmacology/Toxicology Coordinating Committee and the Center's review divisions.

Establishes and maintains a computerized toxicology knowledge database using data derived from Center files in areas such as carcinogenicity, reproductive toxicity, developmental toxicity and genotoxicity. Application of this resource includes regulatory review support, international harmonization,

and the development of Center regulatory policy and guidance.

Evaluates the potential application of computer-based toxicology predictive modeling systems for pharmaceuticals. Utilizes toxicology information in Center databases to enhance the predictive power of modeling systems for pharmaceuticals.

5. Insert the following new subparagraphs under the Laboratory of Clinical Pharmacology (HFNSD-2), *Office of Testing and Research (HFNSD)* reading as follows:

Laboratory of Clinical Pharmacology (HFNSD-2). Serves as the Center's principal resource for laboratory research which is related to the discipline of clinical pharmacology.

Develops preclinical model systems which assist in expediting the initiation of early clinical trials.

Collaborates with the Office of Clinical Pharmacology and Biopharmaceutics and other Center components on appropriate research.

Collaborates in joint projects with other Government agencies.

6. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: December 27, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 97-1201 Filed 1-16-97; 8:45 am]
BILLING CODE 4160-01-F

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Area Health Education Centers (AHEC) and Health Education Training Centers (HETC): Managed Care Inventory Project—New—Section 746(a) of the Public

Health Service Act authorizes Federal assistance to schools of medicine (allopathic and osteopathic) which have cooperative arrangements with one or more public or nonprofit private area health education centers (AHECs) for the planning, development and operation of area health education center programs. Section 746(f) of the PHS Act authorizes Federal assistance to schools of allopathic and osteopathic medicine, or parent institutions on behalf of such schools, or a consortium of such schools to plan, develop, establish, maintain or operate HETCs. The support is designed to improve the supply, distribution, quality, and efficiency of (a) personnel providing health services in the State of Florida or along the border between the United States and Mexico and (b) personnel providing, in other urban and rural areas of the U.S., health services to any population group, including Hispanic individuals and recent refugees, that have demonstrated serious health care needs. Program support is also used to encourage health promotion and disease prevention through public education.

A telephone survey is proposed of federally funded AHEC and HETC programs to determine the variety and extent of managed care training activities that are ongoing or planned within the next two years. The survey results will be used to formulate recommendations for managed care training, and to help guide the AHEC/HETCs in planning and directing training programs and clinical experience in managed care. The burden estimates are as follows:

Type of center	No. of re-pond-ents	Re-sponses per re-pond-ent	Hours per re-sponse	Total burden hours
AHECs	36	1	2 hrs	72 hrs.
HETCs	10	1	2 hrs	20 hrs.
Total	46	1	2 hrs	92 hrs.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 14, 1997.
J. Henry Montes,
Director, Office of Policy and Information Coordination.
[FR Doc. 97-1260 Filed 1-16-97; 8:45 am]
BILLING CODE 4160-15-P

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

The Health Resources and Services Administration is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Subtitle 2 of Title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act

of 1986 and as amended, governs the VICP. The VICP, administered by the Secretary of Health and Human Services (the Secretary), provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition with the United States Court of Federal Claims. In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and