

and management consulting and office services.

Plans and develops management policies and programs which support operations of all Office components.

Develops and conducts evaluation studies to determine the effectiveness of Center and Office programs, policies, and priorities and to forecast workloads to determine resource allocations and select alternative operating plans. Proposes improvements in program effectiveness and efficiency.

Monitors workflow to determine that program goals and objectives are met.

Office of Clinical Pharmacology and Biopharmaceutics (HFNSA). Evaluates pharmacokinetic, pharmacodynamic, bioavailability, bioequivalence, and drug metabolism protocols and data in notices of claimed investigational exemption for new drugs (INDs), new drug applications (NDAs), antibiotic applications (Form 5), and their supplements and amendments.

Approves, disapproves, or recommends new bioavailability, bioequivalence, pharmacokinetic, pharmacodynamic, and drug metabolism studies and/or protocols.

Identifies potential clinical pharmacology and biopharmaceutical problems and prepares protocols and guidelines for conducting relevant studies.

Reviews and evaluates drug disposition data, dosing regimen, and specialized drug delivery systems to assure drug bioavailability.

Initiates, monitors, and conducts biopharmaceutical research.

Office of Generic Drugs (HFNSB). Oversees the development and implementation of standards for the safety and effectiveness of generic drugs.

Reviews and evaluates Abbreviated New Drug Applications (ANDAs), Abbreviated Antibiotic Drug Applications (AADAs), and their amendments or supplements and determines approvability.

Establishes bioequivalency specifications for drug products and develops guidelines for bioequivalency reviews, industry protocols, and studies.

Oversees all aspects of labeling submissions for ANDAs and AADAs.

Office of New Drug Chemistry (HFNSC). Manages the science issues of chemistry, microbiology, manufacturing, and control reviews and ensures consistency in new drug chemistry reviews.

Manages the overall coordination for IND and NDA chemistry and microbiology review processes within the Office.

Reviews and evaluates the chemistry and microbiology portion of INDs, NDAs, amendments, and supplements for drugs regulated by this Office and recommends appropriate action with respect to safety.

Evaluates manufacturing methods, controls, and facilities of manufacturers of drugs submitted for approval in NDAs for drugs regulated by the Office.

Develops policy and procedures governing the chemistry and microbiology review and evaluation of INDs and NDAs.

Provides advice and information to other components of the Center and the Agency on chemistry, manufacturing, and control issues as they relate to human drugs regulated by the Center.

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.

Coordinates Centerwide research activities in biomathematical/statistical, pharmaco-epidemiological, econometric, and regulatory process or administration-oriented subject areas.

Coordinates basic and applied pharmaceutical research including in vitro physicochemical or analytical biochemistry studies and in vivo rodent, nonhuman primate, and human clinical research.

Develops and coordinates Center extramural research policy and monitors research projects.

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 other Agency components, educates the public on Center and Agency policy and activities.

3. 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: September 1, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95-25326 Filed 10-12-95; 8:45 am]

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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 at 59 FR 43128, August 22, 1994) is amended to reflect the transfer of the International Affairs Staff from the Office of Health Affairs to report directly to the Deputy Commissioner for External Affairs, Office of External Affairs (OEA), in the Food and Drug Administration (FDA). Chapter HF is further amended to establish the Industry and Small Business Liaison Staff.

The International Affairs Staff will continue to serve as the Agency focal point for developing and maintaining international communications and programs. FDA believes that the increase in international activity with regard to FDA regulated products and activities necessitates the elevation of the International Affairs Staff to the office level within OEA and that this action enhances the management and coordination of Agency international activities.

The Office of External Affairs has realigned its industry liaison functions within the immediate office of the Deputy Commissioner for External Affairs and established a new Industry and Small Business Liaison Staff. The new staff will serve as the Agency focal point for overall industry liaison and communication activities within FDA. FDA believes that stronger emphasis should be placed on promoting understanding of and compliance with FDA regulations among regulated industry, industry trade and scientific associations, and professional societies.

Under section HF-B, Organization:

1. Delete the subparagraph *International Affairs Staff (HFA56)*, under the *Office of Health Affairs (HFA5)*, in its entirety and insert a new subparagraph, *International Affairs Staff (HFAQA)*, under the Office of External Affairs (HFAQ), reading as follows:

International Affairs Staff (HFAQA). Serves as the Agency focal point for developing and maintaining international communications and programs.

Establishes and provides an Agency liaison on international activities with the Department, Public Health Service (PHS), and other Federal agencies, foreign governments, including foreign

embassies, and international organizations.

Represents the Agency at meetings, conferences, and symposia relating to international obligations; briefs Agency participants in such international activities.

Establishes, identifies, interprets, and clarifies, in cooperation with appropriate Agency components, the Agency's international obligations and needs, including those associated with bilateral programs which involve extra budgetary support.

Establishes and maintains an international information exchange program concerning Agency policies and programs to provide interchange between FDA and counterpart agencies in foreign countries and international organizations.

Assists in the development, negotiation, and monitoring of agreements with foreign governments and international organizations in cooperation with appropriate Agency components; and acts as the Agency focal point for intergovernmental conferences.

Negotiates the preparation and implementation of technical assistance programs (including formal training programs and surveys) with foreign governments and international organizations in areas relating to the Agency mission. Coordinates ongoing technical assistance operations with appropriate components within the Department, PHS, and the Agency.

Directs the Agency's International Visitors Program, providing participants with policy briefings, technical training, and/or assistance in response to specific needs.

2. Insert a new subparagraph, *Industry and Small Business Liaison Staff (HFAQB)*, under the *Office of External Affairs (HFAQ)*, reading as follows:

Industry and Small Business Liaison Staff (HFAQB). Advises and assists the Commissioner and other Agency officials on industry-related issues which have an impact on policy, direction, and goals.

Serves as the Agency focal point for overall industry liaison and communication activities within FDA, including FDA centers, and between FDA and FDA-regulated industry, industry trade associations, and scientific associations.

Serves as a liaison with other Agency components to provide advice and assistance to small manufacturers and scientific associations to promote their understanding of and compliance with FDA regulations.

Develops and maintains effective channels of communication with

regulated industry, professional societies, and trade and scientific associations.

3. 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: September 11, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

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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 at 53 FR 8978, March 18, 1988) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The Office of Management, Center for Drug Evaluation and Research (CDER) is being revised to update its current functional statements to more accurately depict the services provided to CDER.

Under section HF-B, Organization:

1. Delete the subparagraph *Office of Management (HFN12)*, under the *Office of the Center Director (HFN1)*, in its entirety and insert a new subparagraph reading as follows:

Office of Management (HFN12). Monitors the development and operation of planning systems for Center activities and resource allocations and advises the Center Director on Center administrative policies and guidelines and information systems and services. Plans and directs Center operations for financial, administrative, and facilities management activities, and office services. Provides service and support on human resource and recruitment activities.

Directs Center organization, management, and information systems.

Coordinates the performance of organization and management studies.

Advises the Center on contract and grant proposals.

Provides coordination for receipt and distribution of initial drug applications and other related documents.

2. 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: September 1, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

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Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (HHS), is publishing the following summaries of proposed collections for public comment. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request*: Extension of a currently approved collection;

Title of Information Collection: Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity, Version I and Version II. (Either version may be used through April 1, 1996);

Form No.: HCFA-R-182;

Use: This information is needed to correctly process claims and insure that claims are properly paid. These forms contain medical information necessary to make an appropriate determination;

Frequency: On Occasion;