

training in most laboratory settings. This project is an evaluation of the effectiveness of the NLTN in meeting its goals and in satisfying the needs of its customers. Recipients of training and their supervisors will be the major sources of information. Some

assessment of participants that have not attended NLTN courses will be necessary to use as a control group.

Surveys will be directed to all types of laboratories that perform diagnostic testing. Samples will be selected from local health department laboratories,

state health department laboratories, microbiology course participants and physician office laboratories. The study was designed in FY 1994 and FY 1995. Data collection should begin late in FY 1995 and be completed in FY 1996.

Respondents	No. of respondents	No. of responses/respondents	Avg. burden/response	Total burden
Laboratories .....	10,000	1	.5	5,000

Dated: October 6, 1995.  
 Joseph R. Carter,  
*Acting Associate Director for Management And Operations, Centers for Disease Control and Prevention (CDC).*  
 [FR Doc. 95-25443 Filed 10-12-95; 8:45 am]  
**BILLING CODE 4163-18-P**

**National Committee on Vital and Health Statistics (NCVHS) Executive Subcommittee; Meetings**

Pursuant to Pub. L. 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following subcommittee meetings.

*Name:* NCVHS Executive Subcommittee.  
*Time and Date:* 9 a.m.-5 p.m., November 8-9, 1995.

*Place:* Auditorium, Oakland Federal Building, 1301 Clay Street, Oakland, CA 94612-5217.

*Name:* NCVHS Executive Subcommittee.  
*Time and Date:* 9 a.m.-5 p.m., December 5-6, 1995.

*Place:* Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

*Status:* Open.

*Purpose:* The purpose of this meeting is to obtain public comments and views toward identifying a set of core health data elements on persons and encounters or events that can serve multiple purposes and would benefit from standardization. This is a public-private collaborative effort by NCVHS to provide information and advice to the Department of Health and Human Services that would help maximize the utility of core person and encounter data and foster evolution of public and private health information systems toward more uniform, shared data standards. The Committee seeks through this effort to facilitate consensus development and build the concepts of multiple use, continued change, and long-term evolution of core data elements into general thinking and practice. The goal is to see what commonalities already exist and to what extent there can be further movement toward greater commonality of terms and consistency of definition. The Committee hopes to provide tentative recommendations to the Department's recently established Data Council by early 1996.

*Matters to be Discussed:* Comments and views of health data collectors and users will be sought on a list of potential core data elements, which includes those that have been recommended or considered by NCVHS for inclusion in the Uniform Hospital Discharge Data Set and Uniform Ambulatory Care Data Set. The list also includes additional elements frequently collected by selected public and private payers and health care plans, as identified through development of a working compendium of core data elements collected or proposed for collection regarding eligibility, enrollment, encounters, and claims in the United States. Agenda items are subject to change as priorities dictate.

Persons wishing to make oral comments at the meeting should notify the contact persons in writing or by telephone no later than the close of business on October 20, 1995. Written comments are welcome and should be reviewed by October 27, 1995. All request to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit each presenter.

Comments received after October 27 but by November 17 will be considered at the December 5-6 meeting. Other oral comments and germane discussion will be accepted at the discretion of the chair and as time permits. Written comments from persons who do not expect to attend either the November 8-9 or December 5-6 meeting should be submitted to the general information contacts listed below. These comments will become a part of the official record of the meeting. Persons with disabilities who require special accommodations are requested to specify their needs in writing to the general information contact persons listed below by October 20, 1995.

*Notice:* In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each meeting day either between 8:30 and 9:00 a.m. or 12:30 and 1:00 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured. In the interest of security at the Oakland Building, persons must present a picture

identification or sign in with the security guard.

*Contact Persons for More Information.* Substantive program and technical information may be obtained from Lynnette Araki or Marjorie S. Greenberg, Office of Planning and Extramural Programs, (OPEP), NCHS, CDC, telephone number 301/436-7142, fax 301/436-4233. For general information on logistics and special needs as well as summaries of the meetings and a roster of committee members please contact Bette Darling, Program Development Staff, OPEP, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436-7122, fax 301/436-4233.

Dated: October 6, 1995.  
 John C. Burckhardt,  
*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*  
 [FR Doc. 95-25442 Filed 10-12-95; 8:45 am]  
**BILLING CODE 4163-18-M**

**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 56 FR 58250, on November 18, 1991) is amended to reflect an organizational change in the Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA).

The Food and Drug Administration plans to realign its major human drug program functions into two primary lead areas: drug review management and pharmaceutical science. The Office of Review Management (ORM) and the Office of Pharmaceutical Science (OPS), each to be headed by a Deputy Center Director, will report directly to the Director of CDER. FDA believes this

reorganization will rebuild and strengthen the existing structure of the new drug review process to more effectively accomplish CDER's mission. The new ORM structure will align the drug review components into smaller, more cohesive offices to allow a more efficient review process and facilitate communication both up and down organizational lines.

The chemistry review function will be separated into an Office of New Drug Chemistry within OPS. In addition, OPS will also oversee the pharmacological, biopharmaceutical, and generic drug review functions. CDER believes the consolidation of these functions will contribute to the quality of chemistry reviews by improving basic management and oversight of the chemistry program. The realignment will also facilitate the development and dissemination of consistent and uniform policies through a single source.

CDER's new organizational structure will streamline its operations while continuing to meet its statutory mandates, the goals agreed to under the Prescription Drug User Fee Act, and the requirements of the National Performance Review.

Under Chapter HF, Section HF-B, Organization:

1. Delete the following subparagraphs under the Center for Drug Evaluation and Research (HFN1) in their entirety *Office of Drug Standards (HFNE)*, *Office of Drug Evaluation I (HFNG)*, *Office of Drug Evaluation II (HFNK)*, *Office of Epidemiology and Biostatistics (HFNJ)*, *Office of Research Resources (HFNL)*, *Office of Generic Drugs (HFNM)*, and *Office Over-the-Counter Drug Products (HFNN)*.

2. Insert the following new subparagraphs under the Center for Drug Evaluation and Research (HFN1) reading as follows:

*Office of Review Management (HFNR)*. Develops and implements the Center's review management and scientific policies, including user fee policies, pertaining to the drug review process.

Reviews investigational new drug applications (INDs) for all classes of drug products for human use with the exception of generic drug applications, and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates for safety and effectiveness and approves new drug applications (NDAs) for drug products for human use.

Coordinates and/or reviews and decides on the appropriate action, including approval or disapproval, of all applications for over-the-counter (OTC) drug products, OTC drug monographs,

prescription drug switches to OTC drug status, and other OTC-related drug products, with the exception of generic drug applications.

Develops and implements standards for the safety and effectiveness of prescription drug products for human use and (OTC) drugs.

Oversees surveillance programs conducted to collect and evaluate the effects and use trends of marketed drug products.

Provides direction and policy formulation for pharmacology/toxicology-related issues for the Center.

In carrying out these functions, cooperates with other FDA components, other PHS organizations, governmental and international agencies, volunteer health organizations, universities, individual scientists, nongovernmental laboratories, and manufacturers of drug products.

*Advisors and Consultants Staff (HFN1-1)*. Directs and manages Center programs involving the use of scientific advisors, consultants, and committees.

Provides direction for Center scientific liaison with medical and scientific communities, industry, and the private sector.

Counsels and coordinates with Center managers on the use of scientific experts and resources.

Develops Center policy and guidelines related to the appointment and utilization of scientific advisors and consultants.

*Office of Drug Evaluation I (HFNRA)*. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based.

Develops policy and procedures governing the review and evaluation of drug investigations and NDAs.

Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office.

Performs consulting medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and

reports submitted by holders of NDAs for products regulated by this Office.

Oversees the development and implementation of standards for the safety and effectiveness of drug advertising and labeling.

Monitors, evaluates, and develops policy for prescription drug promotion and labeling.

Initiates necessary actions to maintain industry compliance with prescription drug advertising and labeling regulations.

Participates in Agency sponsored consumer and professional educational programs on drug standards.

*Office of Drug Evaluation II (HFNRB)*. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based.

Develops policy and procedures governing the review and evaluation of drug investigations and NDAs.

Evaluates and takes appropriate action on recommendations concerning withdrawal of approval for NDAs for products regulated by this Office.

Performs consulting medical and scientific evaluations of submission on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs for products regulated by this Office.

*Office of Drug Evaluation III (HNNRC)*. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based.

Develops policy and procedures governing the review and evaluation of drug investigations and NDAs.

Evaluates and takes appropriate action on recommendations concerning withdrawal of approval of NDAs for products regulated by this Office.

Performs consulting medical and scientific evaluations of submissions on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs for products regulated by this Office.

*Office of Drug Evaluation IV (HFNRD)*. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates for safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based.

Develops policy and procedures governing the review and evaluation of drug investigations and NDAs.

Evaluates and takes appropriate action on recommendations concerning withdrawal of approval for NDAs for products regulated by this Office.

Performs consulting medical and scientific evaluations of submission on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs for products regulated by this Office.

*Office of Drug Evaluation V (HFNRE)*. Reviews notices of claimed investigational exemptions for new drugs (INDs) within classes of drugs regulated by this Office and recommends appropriate action with respect to safety and effectiveness of clinical trials.

Evaluates the safety and effectiveness and approves new drug applications (NDAs) for products regulated by this Office, and evaluates supplements that propose changes in the conditions upon which NDA approvals are based.

Evaluates for safety and effectiveness and approves applications for over-the-counter (OTC) drug products.

Oversees the development of policy and procedures governing the review and evaluation of drug investigations, NDAs, and OTCs.

Evaluates and takes appropriate action on recommendations concerning withdrawal of approval for NDAs for products regulated by this Office.

Performs consulting medical and scientific evaluations of submission on generic drugs, drugs under monograph, and over-the-counter drug products regulated by other offices in the Center.

Conducts, in coordination with other Agency components, continuing surveillance and medical evaluation of labeling, clinical experience, and reports submitted by holders of NDAs for products regulated by this Office.

*Office of Epidemiology and Biostatistics (HFNRG)*. On behalf of both CDER and CBER, conducts programs to collect and evaluate epidemiological and nonepidemiological information on drug and biological product usage, adverse reactions, poisonings, safety, quality, and effectiveness.

Disseminates drug and biological product information to other components of the Center and the Agency.

Collaborates with users of drug and biological product information to insure that information collected and evaluated is sufficient, relevant, and useful.

Provides statistical services to Center scientific and regulatory programs.

Conducts research on, develops, and evaluates statistical methodologies.

Conducts research and develops information using epidemiological and other strategies to determine the best way to communicate drug and biological product usage information to health professionals and consumers.

Develops liaison with sources of medical and scientific information related to drugs and biological products.

*Office of Pharmaceutical Science (HFNS)*. Provides advice and information to other components of the Center and the Agency on pharmaceutical programs and issues.

Oversees research and development of scientific standards on the composition, quality, safety, and effectiveness of human drug products and provides expert advice based on that research in support of the drug review regulatory process.

Oversees the development of standards for the safety and effectiveness of generic drugs.

Oversees the review and evaluation of Abbreviated New Drug Applications (ANDAs), Abbreviated Antibiotic Drug Applications (AADAs), and their amendments or supplements and determines approvability.

Oversees the science issues of chemistry, manufacturing, and control reviews; ensures consistency of new drug chemistry reviews; and manages the overall coordination of IND and NDA chemistry reviews.

Oversees the review and evaluation of pharmacokinetic, pharmacodynamic,

drug metabolism, bioavailability, and bioequivalence protocols and data in INDs, NDAs, antibiotic applications and their supplements and amendments.

Oversees the FDA's insulin certification program.

Oversees the testing of drug samples obtained for compliance programs, evaluation of methods in new drug applications, approval in the abbreviated new drug application process, and special investigations or testing for other scientific and regulatory components of the Agency.

*Chemistry Policy 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.

Advises and assists Center management on program and policy issues concerning compendial operations.

*Formulations Research Staff (HFNS2)*. Oversees scientific activities which form the basis for regulatory approval of drug substances and products within CDER.

Facilitates scientific investigations which result in the development of tests and specifications to assure the performance of drug products.

Manages and oversees extramural research contracts which provide data in support of regulatory standards, policies, and decisions.

*Operations Staff (HFNS3)*. Advises the Deputy Director for Pharmaceutical Science on all administrative management matters relating to the day-to-day activities of the Office of Pharmaceutical Science.

Provides direct administrative support to the Office in the areas of financial and personnel management

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