

agency task forces and committees reviewing and developing uniform data elements and data sets for diverse health care settings, nomenclatures and classifications; (5) serves as a focal point within NCHS for collaborative activities related to computer-based patient record development; (6) supports the Director, NCHS, as a member of the DHHS Data Council and coordinates NCHS staff support to the Data Council for data policy and standards activities; (7) serves as a focal point for programmatic and subject matter support of the NCVHS; (8) establishes and maintains liaison between NCVHS and agencies within DHHS, other governmental agencies, and relevant private and professional organizations; (9) directs and facilitates cross-cutting national data policy activities that involve multiple outside organizations and have important implications for NCHS and CDC programs; (10) provides liaison with standard-setting organizations on emerging data needs and on medical and health classification issues; (11) is responsible for overseeing, coordinating, evaluating, and formulating recommendations for the ICD Family of Classifications and related classifications, by providing the focus within NCHS for the development and execution of classification activities; (12) serves as the focal point and coordinator of U.S. Government activities related to the ICD and maintains liaison with the World Health Organization (WHO) through direction of the WHO Collaborating Center for the Classification of Diseases for North America; (13) provides advice and assistance within NCHS and to other agencies and organizations in the conduct of training activities related to data policies and standards; conducts training in key areas as appropriate; and promotes appropriate training and educational materials for implementation and use of data sets and classification systems; (14) assures comparability of morbidity classification, using current and subsequent versions of the ICD for morbidity, and recommends revisions to the ICD for morbidity applications as appropriate; (15) assumes full responsibility for the development and implementation of the evaluation program of NCHS for assessment of the adequacy, completeness, and responsiveness of Center programs both nationally and internationally to the NCHS mission and user needs for data; based on evaluations, makes proposals for changes in NCHS programs or policies; (16) assures and provides interface of data confidentiality, linkage,

and security issues with other data policies and standards; and (17) participates with appropriate agencies and organizations to promote the dissemination, adoption, and use of data policies and standards advocated by NCHS, DHHS, and the NCVHS; develops comprehensive policy analyses and special reports, and newsletters.

Program Development Staff (HCS163).

(1) Develops, pilots, and promotes programs, projects, and special activities to improve and quality, comparability, timeliness, and particularly, the relevance of data with emphasis on those aspects of data collection, analysis, interpretation, and dissemination that require collaboratively-supported systems involving public and private agencies, all levels of government and the international statistical community; (2) develops and conducts specialized workshops and conferences to build focused research capacities and foster networks of extramural researchers; (3) promotes public/private extramural funding opportunities through identifying common needs and developing innovative research strategies; (4) develops innovative training programs, materials, and substantive guidelines for use in collaboratively-sponsored and coordinated health statistics activities; (5) responds to unique requests for improved approaches or assistance in the planning and conduct of complex statistical enterprises, particularly those involving major policy issues, multiple agencies or levels of government, and operating at the intersect of public health practice and epidemiologic or statistical operations and research; (6) conducts other activities and participates in special projects selected to provide NCHS an opportunity for gaining definitive knowledge regarding major priority needs for data and major barriers to success in collaboratively-sponsored statistical enterprises, with emphasis on projects requiring data for subnational geographic areas and special populations and for multiple levels of government; (7) serves as the focal point for coordination of health statistical activities within NCHS as they relate to data needs and applications by other organizations or agencies; (8) provides program leadership for the NCHS Reimbursable Work Program including the private sector initiatives; (9) provides liaison with other federal departments and encourages interagency collaboration through the conduct of formal interagency meetings, seminars,

workshops, and conferences which are designed to promote coordination of NCHS data systems with other federal, national, and international health systems; (10) participates in the dissemination, evaluation, and use of standard health data sets; (11) directs research and development related to data systems for community health profiles and other small area applications; (12) participates in the NCHS longitudinal studies program development and implementation; (13) designs and implements special studies related to other assigned functions; and (14) prepares committee charters and proposals for the establishment or termination of committees and subcommittees, prepares nominations for submission to the Secretary, DHHS,

Dated: April 4, 2002.

David W. Fleming,

Acting Director, CDC.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 66 FR 39178-39179, dated July 27, 2001) is amended to reorganize the National Center for Infectious Diseases.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete the functional statement for the *National Center for Infectious Diseases (HCR)* and insert the following:

Plans, directs, and coordinates a national program to improve the identification, investigations, diagnosis, prevention, and control of infectious diseases. In carrying out the mission, the Center: (1) Provides leadership in investigation and diagnosis of infectious diseases of public health significance; (2) maintains surveillance of infectious diseases, disability, and death; (3) conducts applied and operational research related to definition, distribution, diagnosis, prevention, and control of infectious diseases, including vaccine development; (4) administers a

biological reagents program which includes research on production, development of guidelines for production and utilization, and standardization, production, and distribution of reference reagents; (5) produces, evaluates and distributes experimental vaccines, antisera and antitoxins, skin test antigens, and immune serum globulins to control and prevent laboratory infections and to prevent or minimize illness in certain production groups; (6) produces and distributes microbiological reference and working reagents not commercially available or of unreliable supply; (7) conducts applied research related to vectors of disease; (8) provides epidemic assistance; (9) maintains competence in the detection, identification, and control of rare, exotic, or tropical diseases; (10) provides reference diagnostic services; (11) provides technical assistance to states and localities and to other nations in the investigation, diagnosis prevention, and control of infectious diseases; (12) provides scientific services in support of CDC's laboratories; (13) provides epidemic aid to foreign nations and assists other nations in establishing and implementing infectious disease control program; and (14) collaborates, as appropriate, with other Centers and Offices of the CDC in carrying out the above functions.

Delete in its entirety the title and functional statement for the *Division of Viral and Rickettsial Diseases (HCRY)* and insert the following:

Division of Viral and Rickettsial Diseases (HCRU). (1) Conducts surveillance, investigations, and studies of viral and rickettsial diseases to define their etiology and epidemiology and to develop effective methods for prevention, diagnosis, treatment, and control; and (2) conducts or participates in clinical, field, and laboratory research to develop, evaluate, and improve laboratory methods, materials, and therapeutic practices used for prevention, diagnosis, treatment, and control of viral, rickettsial, and prion diseases; (3) conducts research on virus transmission to develop effective prevention and control strategies and on vaccine effectiveness to assess prevention potential; (4) conducts laboratory, clinical, and epidemiologic studies of highly hazardous disease agents that require biosafety level 3 or biosafety level 4 security for their safe handling; (5) conducts ecological studies to develop and evaluate disease prevention and control measures; (6) provides epidemic aid, epidemiologic consultation, reference and diagnostic services, and technical assistance to

state and local health departments, other federal agencies, and national and international health organizations; (7) provides scientific and technical assistance to other National Center for Infectious Diseases (NCID) and Centers for Disease Control and Prevention (CDC) components when the work requires unique expertise or specialized equipment not available in other components; (8) provides routine and specialized laboratory training in the diagnosis, isolation, and characterization of viral and rickettsial agents to personnel from state and local health departments and other national and international organizations; (9) provides training opportunities for Epidemic Intelligence Service officers and others in CDC sponsored programs, including postgraduate students, postdoctoral fellows, and other public health and laboratory scientists; (10) provides expert pathological support for various infectious diseases to state and local health departments, other NCID components, and national and international organizations; and (11) serves as appropriately designated national and World Health Organization collaborating centers for viral and rickettsial diseases.

Office of Director (HCRU1). (1) Directs and administers the programs and activities of the Division of Viral and Rickettsial Diseases (DVRD); (2) provides leadership and counsel on policy development and interpretation, budget formulation, and program planning, development, management, operations, and evaluation; (3) provides DVRD-wide administrative and programmatic services and coordinates or ensures coordination with the appropriate NCID or CDC staff offices; (4) provides liaison with other governmental agencies, international organizations, and other groups; (5) coordinates, in collaboration with the appropriate NCID and CDC components, international health activities related to the prevention and control of viral, rickettsial, and prion diseases; (6) coordinates, in collaboration with the appropriate CDC, PHS, and non-governmental components, CDC's activities to monitor and improve the safety of blood and blood products in the United States and international settings, including development and enhancement of surveillance systems, conduct of epidemic investigations and risk assessment studies, and development and evaluation of prevention strategies; (7) serves as a liaison between CDC and other PHS agencies, the Department of Health and Human Services, non-governmental

organizations, and professional groups on blood safety issues through active participation in federal advisory committees and technical committees; (8) conducts surveillance and epidemiologic investigations to facilitate the understanding and control of prion diseases, Reye syndrome, and Kawasaki syndrome; (9) serves as the primary disseminator of information from CDC, including clinical and disease prevention consultations to state and local health departments and/or federal and international agencies on the illnesses and syndromes caused by or related to viruses, rickettsiae, and prions; (10) augments the statistical and epidemiologic resources for the branches within the Division through provision of consultations and support for specific projects or investigations and helps develop, support, and coordinate statistical activities at the division level; (11) provides scientific and editorial review and clearance of manuscripts for publication, abstracts for presentation, protocols for Institutional Review Board (IRB) and human subjects review, and other scientific, programmatic, and informational materials; and (12) coordinates the implementation of a comprehensive public health communication program for the prevention and control of diseases caused by viruses, rickettsiae, and prions.

Information Technology Activity (HCRU12). (1) Designs, implements, and maintains network systems for internal and external user connectivity for accessing, transferring, and storing data; (2) provides user support for desktop operating systems and software; (3) continuously consults with user community to ascertain information technology needs and to develop strategic and action plans; (4) provides technical expertise in the design, development, and support of database management systems; (5) in collaboration with other branches and activities, develops systems to facilitate the acquisition of surveillance data electronically; (6) represents the division on NCID and CDC workgroups and councils and in other IRM related activities; (7) provides graphic support for presentation and desktop publishing; (8) provides intranet services, technical expertise, and support for the development and implementation of web services; (9) provides technical and cost related consultation to DVRD's Office of the Director and Branches; (10) provides assistance to the end-user community for understanding new technology through information

dissemination, coordination, and establishment of training; and (11) provides assurance that IRM regulations, policies, procedures, and standards are incorporated into the Division's information technology plans and activities.

Infectious Disease Pathology Activity (HCRU13). (1) Serves as a scientific and technical resource to NCID by providing expertise in histopathology, molecular pathology, and ultrastructural analysis for detecting infectious disease agents and studying the interactions between microbial agents and host cells; (2) develops, improves, evaluates, and applies special immunohistologic, ultrastructural, and/or nucleic acid probe technologies for detecting microbial agents and/or expressed gene products in tissue specimens or tissue culture; (3) conducts basic and applied research into the pathogenesis of infectious diseases; (4) provides intramural and extramural technical and professional expertise for assistance in training in infectious disease pathology and molecular approaches to the identification of specific nucleic acid sequences and special antigens in tissue specimens; (5) provides for tracking, distribution, and testing of reference/diagnostic pathology specimens submitted through the data and special handling system; (6) provides histopathology, molecular pathology, and ultrastructure reference/diagnostic support and epidemic aid to state and local health departments, other federal agencies, and national and international health organizations; and (7) serves as the WHO Collaborating Center for Reference Pathology of Hemorrhagic Fevers and other Infectious Diseases.

Influenza Branch (HCRU2). Provides leadership and technical expertise for national and international programs aimed at improving the prevention and control of both epidemic and pandemic influenza. In carrying out this mission, the Influenza Branch: (1) Conducts global and national surveillance to identify novel variants with the potential to cause influenza epidemics and pandemics and monitors associated disease activity; (2) conducts investigations of important or unusual international and domestic influenza outbreaks; (3) conducts epidemiological and laboratory investigations to increase knowledge about influenza and to improve its prevention and control; (4) provides information and recommendations on the use of vaccines, antiviral agents, and other modalities to prevent, control, and treat influenza; (5) serves as the WHO Collaborating Center for Reference and Research on Influenza; (6) provides

influenza reagents to World Health Organization Collaborating Laboratories worldwide and maintains a reference collection of human, swine, and avian influenza viruses and antisera; (7) performs reference antigenic analysis, molecular biologic analysis of influenza virus isolates, and post-vaccination human serologic studies for vaccine strain selection; (8) conducts studies into the evolution, structure, replication, immunology, and pathogenesis of influenza viruses; (9) evaluates influenza vaccine and antiviral agents developed elsewhere; (10) develops and evaluates novel, improved influenza vaccines and vaccines that might be used in the case of an influenza pandemic; (11) develops, evaluates, and improves new techniques and reagents for the diagnosis of influenza in humans as well as the rapid identification of avian and swine influenza viruses that may cause human infections; (12) supports applied research directed toward improved influenza prevention and control; (13) provides support for national epidemiologic and laboratory capacity building; (14) initiates and conducts national and international laboratory and epidemiologic training courses; and (15) provides technical expertise and leadership for national and international pandemic planning activities.

Epidemiology Section (HCRU23). (1) Conducts national surveillance and assists with global surveillance to monitor influenza viruses and their impact on populations; (2) conducts investigations of unusual or important influenza outbreaks; (3) conducts research on the control, prevention, surveillance, and epidemiology of influenza; (4) develops, implements, and evaluates strategies and recommendations, including those related to use of vaccines, drugs, and other measures, for the control and prevention of influenza; (5) provides expert consultation and information on the control, prevention, diagnosis, and treatment of influenza; and (6) provides instruction on the epidemiology and surveillance of influenza.

Molecular Genetics Section (HCRU22). (1) Applies molecular biological and genetic techniques to analyze the evolution of human influenza viruses; (2) performs molecular analysis of novel influenza viruses isolated from humans that are submitted to the WHO Collaborating Center for Reference and Research on Influenza; (3) develops vaccines against novel influenza viruses using genetic and recombinant DNA techniques; (4) conducts studies on live attenuated

influenza vaccines to determine the molecular correlates of attenuation and their genetic stability; (5) uses molecular biological techniques to determine the genetic basis for specific phenotypes of influenza viruses such as altered host-range, virulence, and antiviral resistance; (6) develops molecular biological methods for the rapid identification of reassortant viruses bearing genes derived from human and avian or swine influenza viruses; and (7) provides molecular biological support for the development of diagnostic tools or tests for influenza.

Immunology and Viral Pathogenesis Section (HCRU24). (1) Evaluates the humoral and cellular immune responses to influenza infection, to conventional vaccines, and to experimental vaccines in humans and in animal models; (2) develops new technologies to monitor host immune responses to human and avian influenza viruses and vaccines; (3) investigates the immunobiology of aging as it relates to immunity to influenza; (4) develops and evaluates strategies of vaccination against pandemic influenza; (5) conducts serological investigations supporting epidemic investigations or field studies related to avian influenza viruses; and (6) investigates the basis of human and avian influenza virus pathogenicity in mammalian species.

Strain Surveillance Section (HCRU25). (1) Identifies and characterizes influenza viruses using serologic and molecular techniques; (2) monitors appearance and spread in humans of influenza variants with epidemic or pandemic potential; (3) provides laboratory support for epidemic investigations or field studies; (4) maintains a reference collection of human and animal influenza viruses and the corresponding antisera; (5) prepares and distributes reagent kits for influenza virus identification to WHO National Influenza Centers worldwide as needed for the identification of viruses that pose a threat to human health; (6) develops and evaluates new reagents and methods to diagnose influenza more rapidly, efficiently, or sensitively; (7) coordinates international surveillance on the occurrence of antiviral resistance among circulating human influenza viruses; (8) collates and disseminates international epidemiological and virological information on influenza; (9) provides laboratory training to personnel from state and local health departments, WHO's National Influenza Centers abroad, and other organizations on laboratory techniques for the isolation, identification, characterization, and molecular analysis of influenza viruses; (10) conducts studies on the immune

response to influenza variants; (11) conducts phylogenetic and evolutionary studies of human or animal influenza viruses of special interest; and (12) conducts special studies designed to assess the efficacy of administering non-standard doses of conventional vaccines and to examine the basis for attenuation of live attenuated influenza vaccines.

Respiratory and Enteric Viruses Branch (HCRU6). (1) Provides reference/diagnostic services and conducts epidemiological studies and multinational surveillance for respiratory and enteric diseases; (2) monitors respiratory and enteric virus diseases through the National Respiratory and Enteric Virus Surveillance System, the National Enterovirus Surveillance System, and the Global Surveillance Program for Wild Polioviruses; (3) conducts clinical and epidemiologic studies and investigates outbreaks related to respiratory and enteric virus diseases; (4) conducts studies of the biology, biochemical and antigenic characteristics, and immunology and pathogenesis of respiratory and enteric viruses and associated disease; (5) develops, analyzes, and improves diagnostic methods and reagents for respiratory and enteric viruses, (6) develops and evaluates vaccines and vaccination programs for measles virus, rotavirus, and non-influenza respiratory viruses; (7) provides support for global eradication of measles virus and poliomyelitis; and (8) serves as the WHO Collaborating Center for Virus Reference and Research for Respiratory Virus Diseases Other Than Influenza, the WHO Collaborating Center for Virus Reference and Research (Enteroviruses), the WHO Collaborating Center for Polio, the WHO Collaborating Center for Rotavirus Investigators, and the WHO Collaborating Center for Measles.

Enterovirus Section (HCRU62). (1) Conducts epidemiologic, laboratory, biologic, and molecular studies of enterovirus infections and develops strategies to prevent the associated diseases; (2) provides reference/diagnostic support for typing enterovirus isolates; (3) develops and evaluates new diagnostic methods for the diagnosis of enteroviral infections; (4) supports surveillance studies of enterovirus infections; (5) initiates and supports epidemiologic and outbreak investigations of enterovirus infections and associated diseases; and (6) provides laboratory training in enterovirus diagnostics for persons from state and local health departments and other nations.

Molecular Virology Section (HCRU64). (1) Plans, directs, and

conducts laboratory studies and programs to support the global poliovirus eradication program; (2) develops and applies new molecular techniques for understanding the clinical, epidemiologic, and biologic characteristics of poliovirus and non-poliovirus enteroviruses; (3) conducts laboratory studies of poliovirus that include developing techniques and reagents to monitor the distribution and spread of wild polioviruses worldwide; (4) supports development of the global poliovirus eradication laboratory network; (5) provides laboratory support for investigations of outbreaks of poliomyelitis and studies of the efficacy of poliovirus vaccines; (6) conducts studies of the mechanisms of genetic change of polioviruses and reversion of oral attenuated poliovaccine virus to virulent wild-like viruses; and (7) serves as a WHO Collaborating Center for Polio.

Respiratory Virus Section (HCRU66). (1) Plans, directs, and coordinates national programs to control and prevent viral respiratory diseases (other than influenza virus) and parvovirus associated disease; (2) conducts epidemiologic, laboratory, and biologic studies of such non-influenza respiratory viruses as adenovirus, coronavirus, parainfluenza viruses, respiratory syncytial virus, and rhinovirus and parvoviruses; (3) provides reference/diagnostic support for identifying respiratory virus and parvovirus virus infections and isolates; (4) develops and evaluates new methods for diagnosing respiratory virus and parvovirus infections; (5) trains persons from state and local health departments and others from throughout the world on methods for diagnosing respiratory virus and parvovirus infections; (6) initiates and supports epidemic investigations of respiratory virus and parvovirus infections and associated diseases; (7) conducts epidemiologic, immunologic, and virologic studies to support development of RSV and parainfluenza virus vaccines; (8) provides laboratory support for studies of diseases of unknown etiology; and (9) serves as a WHO Reference Center for Respiratory Viruses Other than Influenza.

Viral Gastroenteritis Section (HCRU68). (1) Plans, directs, and coordinates the national program to prevent and control viral gastrointestinal diseases; (2) conducts epidemiologic, laboratory, biologic, and molecular studies of the viral agents of gastroenteritis, including rotaviruses, caliciviruses, astroviruses, Norwalk and Norwalk-related viruses, and enteric adenoviruses, including those

transmitted by food and water, in order to design prevention strategies and improve the health of the public; (3) provides reference/diagnostic support for identifying agents of viral gastroenteritis; (4) develops and evaluates new methods for diagnosing viral gastroenteritis; (5) collaborates and supports studies on effectiveness of vaccine candidates; (6) trains persons from state and local health departments and others from throughout the world on methods for diagnosing viral gastroenteritis; (7) initiates and supports epidemic investigations of gastroenteritis; (8) provides laboratory support for studies of disease of unknown etiology; and (9) serves as a WHO Collaborating Center for Rotavirus Investigators.

Measles Virus Section (HCRU69). (1) Plans, directs, and coordinates laboratory-based surveillance, including serological and molecular surveillance, conducts applied research programs and supports domestic and regional efforts in the elimination of measles and rubella viruses, and supports global programs dedicated to the accelerated control and elimination of these agents; (2) develops and applies new molecular and immunological techniques for understanding the clinical, epidemiologic, and biologic characteristics of measles and related virus infections, including rubella and mumps; (3) uses existing and/or developments diagnostic and immunological assays to determine the immunological correlates of short- and long-term protective immunity that results from the administration of current measles vaccines and/or from wild type measles virus infections; (4) conducts studies of the extent and importance of antigenic and genetic differences among wild-type measles virus isolates and currently used vaccine virus strains; (5) collaborates in the development of live, subunit, and DNA vaccines and alternative delivery routes; (6) evaluates live and/or subunit vaccines in appropriate animal model systems; (7) provides laboratory support for outreach identification and control, for vaccine trials, and for other studies of mutual interest between NCID/NIP and state and territorial laboratories pertaining to measles, mumps, and rubella; (8) serves as WHO Collaborating Center for Measles and Rubella, WHO Global Specialized Measles Laboratory, and PAHO Regional Reference Laboratory for measles and rubella; and (9) provides laboratory training to personnel from state and local health departments and other national and international organizations on measles

and rubella virus diagnostic serology, virus isolation, and molecular epidemiology.

Special Pathogens Branch (HCRU7).

(1) Provides epidemic aid and conducts epidemiologic studies on the detection, prevention, and control of highly hazardous viral diseases; (2) provides primary isolation, identification, and characterization of highly hazardous disease agents that require biosafety level 3 or biosafety level 4 laboratory conditions for their safe handling; (3) develops, evaluates, and improves methods for treatment, prevention, and laboratory diagnosis of hazardous disease agents; (4) conducts laboratory, clinical, and epidemiologic investigations on the pathogenesis, pathophysiology, and prevention of viral infections caused by highly hazardous viruses; (5) provides consultation on the clinical and epidemiologic management of suspected cases and/or epidemics of these diseases, including rapid development of a field laboratory; (6) consults with national and international scientists on the design, staffing, and efficient operation of a high hazard pathogen laboratory program; (7) serves as a WHO Collaborating Center for Virus Reference and Research for Viral Hemorrhagic Fevers; and (8) develops and evaluates health education programs for educating the general public and health professionals about infection, treatment, infection control in clinical settings, prevention, and laboratory diagnosis of highly hazardous viral diseases;

Disease Assessment and Control Section (HCRU74). (1) Provides assessment and integration of ecological, epidemiological, and laboratory aspects of infection, disease, and prevention of highly hazardous viruses; (2) provides primary isolation, identification, and characterization of highly hazardous disease agents that require biosafety level 3 or 4 laboratory standards for their safe handling; (3) develops, evaluates, and improves methods for treatment, prevention, and laboratory diagnosis of hazardous disease agents; (4) consults with national and international scientists on the design, staffing, and efficient operation of a high hazard pathogen laboratory program; and (5) serves as the main focus for activities of the Special Pathogens Branch as a WHO Collaborating Center.

Molecular Biology Section (HCRU75).

(1) Conducts original studies using molecular biological techniques to better understand the biology of highly hazardous viruses; (2) uses most efficient methods for molecular characterization of newly identified

viruses or strains, including PCR, cloning, and sequencing of virus genes and protein characterization; (3) applies current molecular biological methods in developing diagnostic and therapeutic reagents, products, and materials for assessment as candidate vaccines for highly hazardous viruses; (4) collaborates with other sections in applying new reagents and products to the understanding of the epidemiology, pathogenesis, immunology and prevention, and therapy of highly hazardous viruses; and (5) collaborates with visiting national and international scientists in characterizing exotic, highly hazardous viruses.

Pathogenesis and Immunology Section (HCRU76). (1) Conducts original studies on the pathogenesis and immunology of highly hazardous virus diseases; (2) conducts studies on the safety of and protection by vaccines against highly hazardous viruses in animal models; (3) uses in vitro models to assess the role of drug and other biologic agents on the pathogenesis and therapy of highly hazardous agents; (4) obtains and characterizes virus isolates from patients suspected of being infected with highly hazardous viruses; and (5) collaborates with visiting scientists and foreign institutions on the study of highly hazardous viruses in laboratory and field projects.

Viral Exanthems and Herpes Virus Branch (HCRU8). (1) Conducts surveillance and laboratory-based epidemiologic studies of chronic fatigue syndrome (CFS); (2) serves as the WHO Collaborating Center for Smallpox and Other Poxvirus Infections and provides reference/diagnostic services for suspected smallpox and other poxvirus infections, with emphasis on bioterrorism; (3) serves as the Varicella Zoster Virus National Laboratory; (4) conducts laboratory-based epidemiologic studies of human papillomavirus (HPV) infection and diseases with emphasis on control/prevention of cervical cancer and recurrent respiratory papillomatosis; (5) conducts laboratory-based epidemiologic studies of herpesviruses, with emphasis on infections in immunocompromised hosts, congenital and perinatal infections, and disease; (6) conducts research concerning human immune responses to herpes, HPV, and poxviruses; (7) develops, evaluates, and improves methods and reagents for rapid diagnosis of viral infections; (8) provides epidemiology, molecular biology, diagnostic serology/virology, and immunology consultation and collaboration to national and international organizations concerning prevention and control of CFS,

poxvirus, HPV, and herpesvirus diseases, virus-associated cancers, and vaccine programs; and (9) provides assistance regarding DNA virus infection and associations between viruses, host genetics, host immune response, and human disease as necessary.

Epidemiology Section (HCRU83). (1) Conducts surveillance and epidemiologic studies of CFS and diseases caused by HPV, herpesviruses, and poxviruses, with emphasis on prevention/control strategies; (2) supports epidemic investigations of poorly defined syndromic illness and diseases associated with poxviruses, HPV, and herpesviruses; (3) provides data processing, statistical consultation, and epidemiologic/statistical collaboration to all sections of VEHB; (4) develops and evaluates data processing and statistical methods applicable to laboratory assays and investigations conducted by VEHB; (5) collaborates with the National Cancer Institute, NIH concerning utilization of epidemiologic and genetic data in bioinformatics; and (6) provides data processing, statistical, and epidemiology consultation and training to personnel from CDC, state and local health departments, and other national and international organizations.

Human Papillomavirus Section (HCRU84). (1) Conducts laboratory-based epidemiologic studies related to the role of HPV infections in human cancers (e.g., cervical cancer); (2) conducts laboratory-based epidemiologic studies of recurrent respiratory papillomatosis; (3) conducts studies of gene expression of CFS; (4) collaborates in the design and conduct of post-infectious fatigues studies and modeling studies of fatigue following immune stimulation; (5) conducts studies of HPV as opportunistic infections in HIV-positive populations; (6) conducts laboratory studies concerning the mechanisms of HPV-induced cervical cancer; (7) conducts laboratory studies to understand the immunology of HPV infection; (8) develops laboratory methods to improve HPV detection and assessment; (9) provides laboratory training and consultation concerning studies of gene expression and bioinformatics; and (10) provides HPV laboratory training and consultation to national, state, local, and foreign authorities concerning cervical cancer control programs.

Herpesvirus Section (HCRU87). (1) Conducts studies on the epidemiology and molecular biology of recently discovered herpesviruses (e.g., HHV-6, HHV-7 and HHV-8); serves as Varicella Zoster Virus National Laboratory to

develop assays and conduct studies assessing the public health impact of immunization against VZV; (3) conducts epidemiology, immunology, and molecular biology studies to design control programs for diseases associated with congenital acquired cytomegalovirus; (4) conducts studies to assess the public health impact of sexually transmitted herpesviruses so as to devise new intervention strategies; (5) conducts studies to assess the public health impact of herpesviruses that are resistant to antiviral drugs; (6) develops, evaluates, and applies new methods for detecting, diagnosing, and understanding the biologic characteristics of human herpesvirus infections; (7) develops and applies new immunologic techniques for characterizing the cellular and humoral immune responses to herpesvirus; (8) develops practical methods for seroepidemiologic studies of these viruses; (9) conducts studies to define the mechanisms and genetic control of herpesvirus latency; and (10) trains laboratorians on molecular techniques and immunological methods for studying herpesvirus infections.

Poxvirus Section (HCRU89). (1) Serves as WHO Collaborating Center for Smallpox and Other Poxvirus Infections; (2) serves as CDC focal point for addressing aspects of bioterrorism involving poxviruses; (3) cooperates with WHO to implement recommendations concerning destruction of smallpox stores; (4) provides reference, diagnostic, clinical, and epidemiologic support for suspected poxvirus infections which may occur worldwide either naturally or as acts of bioterrorism; (5) conducts laboratory studies to develop, evaluate and improve viral and serologic diagnostics that enhance surveillance and counter terrorism activities to control human poxvirus infections; (6) conducts molecular biologic studies to better understand the basis of poxvirus biotype and virulence; and (7) provides laboratory training to personnel from state and local health departments and other national and international organizations on poxvirus diagnostics.

Viral and Rickettsial Zoonoses Branch (HCRU9). (1) Provides epidemic aid, consultation, surveillance, and epidemiologic and ecologic investigations of viral, rickettsial, and bartonella-associated zoonoses domestically and internationally; (2) conducts studies on the microbiology, molecular biology, pathogenesis, and pathology of viral, rickettsial, and bartonella-associated zoonotic infections; (3) provides reference/diagnostic services domestically and

internationally; (4) develops, evaluates, and improves methods and reagents for diagnosing viral, rickettsial, and bartonella-associated diseases; (5) develops and evaluates human and animal vaccines and other prophylactic agents for zoonotic diseases and prepares recommendations for their use; (6) serves as a WHO Collaborating Center for Reference and Research on Rabies and a WHO Collaborating Center for Rickettsial and Bartonella-associated Reference and Research; (7) provides consultation and laboratory training to state and local health departments and other national and international organizations; (8) responds to requests for information regarding viral, rickettsial, and bartonella-associated zoonotic diseases and their prevention from CDC, health care providers, academic institutions, state, and local health departments, other government agencies, and the general public; (9) collaborates with government agencies, domestic and international academic institutions, and the private sector in developing novel diagnostic assays and vaccines for viral, rickettsial, and bartonella-associated zoonotic diseases; and (10) maintains the Bioterrorism Laboratory for *Coxiella burnetii* (Q fever) and rickettsial response and research.

Disease Assessment and Epidemiology Section (HCRU93). (1) Conducts/coordinates surveillance of human and animal rabies, Lyssaviruses, Rocky Mountain spotted fever, Q fever, the ehrlichioses, bartonella-associated diseases, and rickettsial diseases; (2) conducts epidemiological studies to determine modes of transmission, risk factors, and natural history of viral, rickettsial, and bartonella-associated zoonoses; (3) conducts testing of human and animal tissues to assist in the diagnosis of rickettsial and bartonella-associated diseases and provides reports and interpretation of results to health care providers; (4) maintains databases on serologic and molecular biologic test results for rickettsial and bartonella-associated zoonotic diseases; (5) provides consultation to local, state, national, and international public health officials and the general public on the diagnosis, prevention, and/or treatment of viral, rickettsial and bartonella-associated zoonotic diseases; (6) investigates outbreaks and conducts epidemiologic investigations of viral, rickettsial, and bartonella-associated zoonoses; (7) assists in producing and evaluating diagnostic tests for rabies, rickettsial, and bartonella-associated infections; (8) evaluates vaccines and other methods of preventing or

controlling viral, rickettsial, and bartonella-associated zoonoses; and (9) coordinates the development of public health policy and recommendations regarding vaccines and prevention strategies for viral, rickettsial, and bartonella-associated zoonoses.

Rabies Section (HCRU97). (1) Serves as a national and international center for reference, training, consultation, and diagnosis of rabies and related zoonoses; (2) develops and evaluates new techniques for rabies diagnosis and distributes reference materials to collaborating laboratories in accordance with CDC and WHO policies; (3) collaborates in the development of new rabies vaccines; (4) conducts studies on rabies pathogenesis; (5) investigates the role of strain variation in the ecology and natural history of rabies virus infection; (6) provides laboratory training on rabies and related viral zoonoses to personnel from state and local health departments, other government agencies, and international governments and organizations; (7) serves as a WHO Collaborating Center for Reference and Research on Rabies; and (8) responds to requests for information from CDC, other government agencies, state and local health departments, health care providers, and the general public.

Rickettsia and Bartonella Section (HCRU98). (1) Conducts microbiologic and molecular biologic research into rickettsiae and bartonellae of public health importance; (2) conducts research into the pathogenesis and pathology of rickettsial diseases; (3) develops and maintains databases containing DNA sequences of targeted genes of interest from rickettsiae and bartonellae; (4) provides for rickettsial and bartonella isolation and assistance in the production of reference reagents; (5) provides consultation services to local, national, and international rickettsiology and bartonella laboratories; (6) develops and evaluates new diagnostic tests for rickettsiae and bartonellae prior to routine use by the Disease Assessment and Epidemiology Section; (7) participates in the production and distribution of rickettsial and bartonella reagents to reference laboratories worldwide in accordance with CDC policies; (8) participates in the development of improved rickettsial and bartonella-associated vaccines; (9) evaluates new therapies and antimicrobial agents for rickettsial and bartonella-associated diseases; (10) serves as a WHO Collaborating Center for Rickettsial and Bartonella-associated Reference and Research; (11) conducts training for

laboratory personnel from state and local public health laboratories as well as other national and international organizations; (12) collaborates with other CDC and government agencies and responds to public inquiries regarding rickettsia, ehrlichia, Q fever, bartonella and other designated zoonoses; and (13) maintains the Bioterrorism Laboratory for Q fever and rickettsial disease response and research.

After the Division of Global Migration and Quarantine (HCR2), insert the following:

Division of Viral Hepatitis (HCR4). (1) Conducts surveillance and special studies to determine the epidemiology and disease burden associated with acute and chronic infections and liver disease associated with hepatitis viruses; (2) conducts epidemiologic and laboratory studies, including outbreak investigations, to determine risk factors for transmission of infections with hepatitis viruses, define the natural history and pathogenesis of these infections, and determine their health impact; (3) conducts epidemiologic, clinical, laboratory, behavioral, and health communications research to develop and evaluate methods and strategies for the prevention of infections with hepatitis viruses and their acute and chronic disease consequences; (4) develops, implements, communicates, and evaluates recommendations and standards for the prevention and control of infections and liver disease associated with hepatitis viruses; (5) provides technical and programmatic leadership and assistance to state and local health departments, non-governmental organizations, and the international community to develop, implement, and evaluate programs to prevent infections with hepatitis viruses and their consequences, including immunization to prevent hepatitis A and eliminate transmission of hepatitis B virus infection, counseling and testing to prevent and control hepatitis C virus infection, and improvement of transfusion and medical practices and reduced frequency of unsafe injections to prevent transmission of bloodborne virus infections, including hepatitis viruses; (6) provides leadership and coordination to integrate viral hepatitis prevention and control activities into other prevention programs conducted by CDC, other Federal agencies, and health care providers; (7) conducts laboratory, clinical, and epidemiologic studies to develop and evaluate methods for the diagnosis of infections with hepatitis viruses; (8) identifies and characterizes agents and host factors associated with hepatitis and acute and

chronic liver disease; (9) provides epidemic aid, epidemiologic and laboratory consultation, reference diagnostic services, and technical assistance to state and local health departments, other federal agencies, other components of CDC, and national and international health organizations; (10) disseminates information through health communications materials, tools and programs, scientific publications, and presentations; (11) provides training opportunities for Epidemic Intelligence Service Officers and others in CDC sponsored programs, including postgraduate students, post-doctoral fellows, and other public health and laboratory scientists; and (12) serves as a WHO Collaborating Center for Reference and Research on Viral Hepatitis.

Office of the Director (HCR41). (1) Directs, administers, and provides oversight for the programs and activities of DVH, including budget formulation and administration; (2) provides leadership and counsel on policy development and interpretation and on program planning, development, management, and evaluation; (3) provides Division-wide administrative and program support services and coordinates and ensures coordination with the appropriate National Center for Infectious Diseases (NCID) and Centers for Disease Control and Prevention (CDC) staff offices; (4) provides the leadership and coordination, including serving on appropriate advisory committees, to integrate viral hepatitis and liver disease prevention and control activities into other prevention programs conducted by NCID, CDC, Department of Health and Human Services, other Federal agencies, international organizations, and other groups; (5) provides leadership and oversight to the provision of state-of-the-art informatics for DVH, including computer systems and equipment, local area networks, computer programs, programming and data management support, and management of DVH internet and intranet websites; (6) provides manuscript review and clearance and coordination and oversight for studies, human subjects review, OMB clearance, Freedom of Information Act (FOIA) requests, other controlled correspondence, and requests for information; (7) coordinates and provides oversight for continuing professional education programs for DVH staff; and (8) provides support to DVH components in writing and editing, preparation of graphics and other visual arts, and conference and

exhibit planning, management, and execution.

Epidemiology Branch (HCR42). (1) Monitors and evaluates rates and risk factors associated with acute and chronic infections with hepatitis viruses, viral hepatitis and liver disease through surveillance systems and special studies, including sentinel surveillance; (2) conducts research, including outbreak investigations, clinical trials and population-based demonstration projects, to determine the epidemiology of transmission of known and new hepatitis viruses and their variants, the natural history of infections with hepatitis viruses, evaluate the performance of diagnostic tests for hepatitis virus infections, and evaluate methods and approaches for the prevention and control of hepatitis virus infections; (3) estimates burden attributable to infections with hepatitis viruses and the effectiveness of programs to prevent these infections; (4) provides consultation to state, local, national, and international authorities for the prevention and control of viral hepatitis, the investigation of disease outbreaks, and surveillance of hepatitis and liver disease; (5) disseminates information through scientific publications and presentations; and (6) provides training opportunities for Epidemic Intelligence Service Officers and others in CDC sponsored programs, postgraduate students, post-doctoral fellows, and other public health scientists.

Prevention Branch (HCR43). (1) Develops, administers, implements, and evaluates domestic and international programs to prevent viral hepatitis, including those that serve clients in the public and private sectors, through state and local health departments, health organizations, academic institutions, and non-governmental organizations; (2) provides leadership and coordination for viral hepatitis and liver disease prevention and control programs with other components of CDC, other Federal agencies, and non-governmental agencies and partners; (3) conducts research to ascertain educational and communication needs, best methods of communication, and effectiveness of educational programs for health professionals, the public, and persons in groups at risk for infection with hepatitis viruses and develops and disseminates accurate, timely and effective educational materials, tools, and programs related to the prevention of viral hepatitis and liver disease; (4) develops and implements accurate, timely, and effective educational tools, materials and programs for prevention of viral hepatitis and liver disease; (5)

develops and conducts studies, including economic and behavioral studies, to evaluate the effectiveness of interventions and programs to prevent viral hepatitis and to identify barriers to prevention services such as immunization, counseling, testing, medical referral, and management; (6) develops and evaluates health services models for prevention of infection with hepatitis viruses and associated liver disease; (7) provides leadership and coordinates the development of national standards and performance objectives for prevention of viral hepatitis and liver disease and works with agencies and partners to adopt these standards; (8) develops indicators and measures by which to evaluate the performance and effectiveness of viral hepatitis prevention programs; (9) disseminates information through scientific publications and presentations; and (10) provides training opportunities for Epidemic Intelligence Service Officers and others in CDC sponsored programs, postgraduate students, post-doctoral fellows, and other public health scientists.

Laboratory Branch (HCR44). (1) Conducts research and applies state-of-the-art laboratory methods in support of studies related to the epidemiology, molecular epidemiology, and natural history of acute and chronic infections with hepatitis viruses and liver disease; (2) conducts research to develop and validate diagnostic approaches to identify infections with hepatitis viruses; (3) develops and evaluates methods to prevent acute and chronic infection and disease outcomes, including vaccines; (4) determines the viral, immunologic, and other host responses to infection with hepatitis viruses in humans and animal models; (5) identifies and characterizes agents that cause hepatitis; (6) provides reference diagnostic testing for markers of infection with hepatitis viruses for state and local public health laboratories; (7) provides the leadership and collaboration to ensure the transfer to public health laboratories, both nationally and internationally, state-of-the-art methods and approaches for the identification and diagnosis of infections with hepatitis viruses; (8) develops and maintains archives of clinical specimens from clinical trials and epidemiologic and laboratory studies; (9) disseminates information through scientific publications and presentations; and (10) provides training opportunities for persons in CDC sponsored programs, postgraduate students, post-doctoral fellows, and other public health scientists.

Dated: April 14, 2002.

David W. Fleming,

Acting Director, CDC.

[FR Doc. 02-9248 Filed 4-16-02; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E-0363]

Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 26, 2002, the comment period for the regulatory review period determination for MIFEPREX, published in the **Federal Register** of January 25, 2002 (67 FR 3724). The agency is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on the regulatory review period determination for MIFEPREX by April 26, 2002.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 25, 2002 (67 FR 3724), FDA published a document entitled "Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX." The document set forth the determination of the regulatory review period for purposes of patent term extension for the human drug product MIFEPREX. The document announced that FDA determined that the applicable regulatory review period for MIFEPREX was 2,249 days, and that of this time, 593 days had occurred during the testing phase of the regulatory review period, while 1,656 days had occurred during the approval phase. The notice explained how these periods of time were derived.

FDA received a letter dated March 22, 2002, from an attorney representing the Population Council (the patent holder) and others, requesting that the agency extend the comment period on the regulatory review period for 30 days, until April 26, 2002, explaining that additional time was needed to reach a licensing agreement. FDA has determined that it is appropriate to grant this request.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the regulatory review period determination for MIFEPREX on or before April 26, 2002. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02-9364 Filed 4-16-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4734-N-14]

Notice of Submission of Proposed Information Collection to OMB; Small Cities Program Performance Assessment Report

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 17, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2506-0020) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number