

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Diseases Control and Prevention****Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Diseases 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 63 FR 34408-09, dated July 16, 1998) is amended to reflect the restructuring of the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Diseases Control and Prevention.

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

Retitle the *Division of HIV/AIDS Prevention (CK2)* to the *Division of HIV/AIDS Prevention—Intervention Research and Support (CK2)*. Delete the functional statement and insert the following:

(1) In cooperation with the CDC components, administers operational programs for the prevention of human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS); (2) provides consultation, training, promotional, educational, other technical services to assist State and local health departments, as well as national, State, and local nongovernmental organizations, in the planning, development, implementation, evaluation and overall improvement of HIV prevention programs; (3) conducts behavioral, communications, evaluation, and operational research into factors affecting the prevention of HIV/AIDS; (4) develops recommendations and guidelines on the prevention of HIV/AIDS; (5) evaluates prevention and control activities in collaboration with other CDC components; (6) provides assistance and consultation on issues related to programmatic support, research, evaluation methodologies, and fiscal and grants management to State and local health departments, nongovernmental organizations, national organizations, and other research institutions; (7) promotes linkages between health department HIV/AIDS programs and other governmental and nongovernmental partners who are vital to effective HIV/AIDS prevention efforts; (8) works

closely with Health Care Financing Administration (HCFA), Health Resources and Services Administration (HRSA), other governmental and nongovernmental agencies, and the managed care community (or the private medical sector) to enhance and evaluate HIV prevention services in public and private health care delivery systems; (9) provides consultation to other Public Health Service agencies, medical institutions, private physicians, and international organizations or agencies; (10) provides information to the scientific community and the general public through publications and presentations; (11) implements national HIV/AIDS prevention public information programs and assists in developing strategic communications activities and services at the national level to inform and educate the American public about HIV/AIDS, especially people whose behavior places them at risk for HIV infection; (12) provides technical support to CDC assignees to State and local health departments who are working on HIV/AIDS prevention and communications activities.

Delete the functional statement for the *Office of the Director (CK21)* and insert the following:

(1) Plans, directs, and evaluates the activities of the division; (2) develops goals and objective and provides national leadership and guidance in HIV/AIDS prevention policy formulation and program planning and development; (3) provides leadership for developing research in behavioral aspects of HIV/AIDS prevention, evaluation of HIV/AIDS prevention, and in coordinating activities between the division and other NCHSTP divisions, CDC Centers, Institute, and Program Offices (CIOs), and national-level prevention partners who influence HIV/AIDS prevention programs involved in HIV/AIDS investigations, research, and prevention activities; (4) in collaboration with other components of CDC and with other governmental and non-governmental organizations, develop and promotes policies and evaluation methods and recommends research to enhance HIV prevention and control efforts in public and private health care delivery systems; (5) provides oversight for human subjects review of protocols and coordinates human subjects review training; (6) coordinates within the division and between the division and the Communications Office, NCHSTP, the response to the national and local communications media on HIV/AIDS issues; (7) ensures multidisciplinary collaboration in HIV/AIDS prevention

activities; (8) provides leadership and guidance for program management and operations and the development of training and educational programs; (9) coordinates the development of guidelines and standards to ensure ongoing, effective HIV prevention programs and their evaluations; (10) oversees the creation of materials designed for use by the media, including press releases, letters to the editor, and other print and electronic materials and programs, and ensures appropriate clearance of these materials; (11) assists in the preparation of speeches and Congressional testimony on HIV/AIDS for the Division Director, the Center Director, and other public health officials; (12) provides program services support in extramural programs management, administrative services, and information systems services; (13) collaborates, as appropriate, with nongovernmental organizations to achieve the mission of the division; (14) provides international consultation in collaboration with the Division of HIV/AIDS Prevention—Surveillance and Epidemiology's lead activity on international HIV/AIDS activities; (15) collaborates with other branches, divisions, and CIOs to synthesize HIV prevention practices; (16) in carrying out these activities, collaborates, as appropriate, with other divisions and offices of NCHSTP, and with other CIOs throughout CDC.

Delete the title and functional statement for the *International Activity (CK211)*.

Delete the title and functional statement for the *Technical Information Activity (CK212)*.

Delete the functional statement for the *Behavioral Intervention Research Branch (CK22)* and insert the following:

(1) Applies current theory, practice, and empirical findings in designing and conducting research on state-of-the-art interventions to prevent HIV infection; (2) conducts research to examine methodological issues related to implementation, design and evaluation aspects of behavioral intervention research trials; (3) conducts research to examine the processes and factors that influence effective and efficient translation, diffusion, and sustainability of behavioral intervention research findings to HIV prevention programs; (4) summarizes and synthesizes the intervention research literature to derive research priorities and specify the characteristics of effective interventions to prevent HIV infection; (5) contributes to the intervention research literature by publishing regularly in peer-reviewed journals and CDC-sponsored publications; (6) collaborates with

Federal, State, and local HIV prevention partners in identifying research priorities and in designing intervention research (7) collaborates and consults with CDC staff, other Public Health Service agencies, State and local health departments, and other groups and organizations involved in HIV prevention activities to devise and facilitate technical assistance systems and activities related to the application of behavioral science research findings to prevention programs and policies.

Delete the functional statement for the *Community Assistance, Planning, and National Partnerships Branch (CK23)* and insert the following:

(1) In collaboration with State and local public health and non-governmental national/regional and local partners, CDC CIOs, and other Federal agencies, develops and implements programs, policies, and activities that enable and mobilize affiliates and communities to become involved with, and support, local and statewide strategic community planning that improves HIV prevention programs and activities; (2) plans, develops, implements, and manages strategies and resources that build a comprehensive public health private-sector partnership to prevent HIV infection/AIDS; (3) provides technical consultation and assistance to State and local health departments, community planning groups, and nongovernmental and other prevention partners in operational aspects of HIV prevention; (4) monitors activities of HIV prevention projects to ensure operational objectives are being met; (5) establishes guidelines and policies for implementation and continuation of State and local HIV prevention programs; (6) provides technical review of grant applications and prevention plans; (7) conducts continuing analysis of support utilization and career development of field personnel and analysis of other resource allocations and utilization in relation to HIV prevention; (8) provides supervision for HIV prevention field staff; (9) assists in the development of new operational programs and program solicitations for HIV prevention; (10) coordinates program development and implementation with State/local/regional community planning groups; (11) facilitates linkages with sexually transmitted diseases (STDs) and other HIV prevention programs at all levels to ensure coordination of harm reduction and intervention strategies for populations with common prevention needs; (12) works with national partners to foster HIV prevention capabilities and activities in affected communities; (13) funds and monitors the progress of

minority and other community-based organizations undertaking HIV prevention programs and activities; (14) develops national public information programs for HIV/AIDS prevention, working closely with behavioral scientists to create communications messages that effectively promote adoption or maintenance of safe behaviors; (15) promotes and facilitates the application of social marketing principles to HIV prevention at the State and local levels; (16) collaborates with external organizations and the news, public service, entertainment, and other media to ensure that effective prevention messages reach the public; (17) in collaboration with the Training and Technical Support Systems Branch, creates and disseminates materials that incorporate prevention marketing principles for use at national, State, and local levels.

Delete the title and functional statement for the *Edipdemology Branch (CK24)*.

Delete the title and functional statement for the *HIV/AIDS Surveillance Branch (CK25)*.

Delete the title and functional statement for the *HIV Seroepidemiology Branch (CK26)*.

Delete the title and functional statement for the *Prevention Communications Branch (CK27)*.

Retitle the *Program Evaluation Branch (CK28)* to the *Program Evaluation Research Branch (CK28)*.

Delete the title and functional statement for the *Statistics and Data Management Branch (CK29)*.

After the functional statement for the *Training and Technical Support Systems Branch (CK2A)*, insert the following:

Technical Information and Communications Branch (CK2B). (1) Evaluates the effectiveness, costs, and impact of HIV prevention interventions, strategies, policies, and programs as practiced or implemented by public health agencies and organizations at the national/regional and State/local levels; (2) collaborates in the application of evaluation findings and techniques to the ongoing assessment and improvement of HIV prevention programs; (3) conducts evaluation research activities that include studies to evaluate the effectiveness and impact of prevention strategies and programs, major prevention activities, and policies; economic evaluations of HIV prevention, including assessments of alternative prevention strategies to encourage the best use of prevention resources; and development of both process and outcome measures that HIV prevention programs can use to assess

their going performance; (4) seeks to advance the methodology of HIV prevention evaluation through evaluation research activities; (5) applies evaluation methods to improving HIV prevention programs, including serving as a resource to other branches/activities, grantees, and prevention partners regarding evaluation of both domestic and international HIV prevention programs; collaborating with other branches as they develop, test, and disseminate models for quality assurance of programs and services; and collaborating with other branches/activities in the development of methods to support the systematic assessment (including self-assessment) and continuous improvement of HIV prevention programs.

After the title and functional statement for the *Surveillance and Epidemiology Branch (CK46)*, *Division of Tuberculosis Elimination (CK4)*, insert the following:

Division of HIV/AIDS Prevention—Surveillance and Epidemiology (CK5). (1) Conducts national surveillance of the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (2) provides consultation and statistical, epidemiological, and other technical services to assist State and local health departments, as well as national, State, and local nongovernmental organizations, in the planning, development, implementation, and overall improvement of HIV prevention programs; (3) conducts epidemiologic, surveillance, etiologic, health services and operational research into factors affecting the prevention of HIV/AIDS; (4) develops recommendations and guidelines on the prevention of HIV/AIDS and associated illnesses; (5) monitors surveillance of risk behaviors associated with HIV transmission; (7) determines risk factors and transmission patterns of HIV/AIDS by conducting national and international HIV/AIDS surveillance, epidemiologic investigations, and research studies; (8) develops preventive health services models for a variety of HIV-related activities; (9) provides assistance and consultation on issues related to epidemiology, surveillance, and research to NCHSTP, CDC, other Public Health Service agencies, State and local health agencies, community-based organizations; CDC prevention partners, medical institutions, private physicians, and international organizations; (10) provides epidemic aid, epidemiologic and surveillance consultation, and financial assistance for HIV/AIDS surveillance activities to State and local

health departments; (11) provides information on HIV/AIDS surveillance and epidemiology to the scientific community and the general public through publications and presentations; (12) works closely with National Center for Infectious Diseases (NCID) on HIV/AIDS surveillance and epidemiologic investigations that require laboratory collaboration, and on activities related to the investigation and prevention of HIV-related opportunistic infections; (13) provide technical support to CDC assignees to State and local health departments who are working on HIV/AIDS surveillance activities; and (14) serves as the World Health Organization (WHO) Collaborating Division on HIV/AIDS for epidemiology and surveillance.

Office of the Director (CK51). (1) Plans, directs, and evaluates the activities of the division; (2) develops goals and objectives and provides national leadership and guidance in HIV/AIDS prevention policy formulation and program planning and development; (3) provides leadership in developing research in epidemiology, surveillance, and other scientific aspects of HIV/AIDS prevention, and in coordinating activities between the division and other NCHSTP divisions, CDC CIOs, and national-level prevention partners who influence HIV/AIDS prevention programs involved in HIV/AIDS investigations and research; (4) provides oversight for human subjects review of protocols and coordinates human subjects review training; (5) maintains lead responsibility for HIV/AIDS issues related to epidemiology, surveillance, or policy; (6) provides leadership and guidance for the development of data management systems; (7) assists in the preparation of speeches and Congressional testimony on HIV/AIDS for the division Director, the Center Director, and other public health officials; (8) coordinates international HIV/AIDS activities of the division and ensures interdivisional coordination of international activists within the center and CDC, as appropriate; (9) provides program services support in extramural programs management, administrative services, and information systems services; (10) collaborates, as appropriate, with nongovernmental organizations to achieve the mission of the division; and (11) in carrying out these activities, collaborates, as appropriate, with other divisions and offices of NCHSTP, and with other CIOs throughout CDC.

Epidemiology Branch (CK52). (1) Designs and conducts epidemiologic and behavioral studies in the United

States to determine risk factors, co-factors, and modes of transmission for HIV infection and AIDS; (2) conducts studies of the natural history of HIV infection, including manifestations of HIV disease in adults, adolescents, and children; (3) designs and conducts research on the psychosocial, cultural and contextual determinants of risk behaviors related to HIV risk behaviors; (4) describes psychosocial impact of HIV on infected individuals, their families, and close contacts and identifies psychosocial and cultural determinants of disease outcomes of HIV-infected individuals; (5) conducts both epidemiologic and behavioral studies to evaluate appropriate biomedical interventions for preventing HIV infection (primary prevention) and for preventing manifestations of AIDS (secondary prevention); (6) conducts applied research, including effectiveness trials, to assist in evaluation of strategies, major activities, and policies; (7) conducts epidemic aid investigations of HIV infection and associated infectious diseases, as well as other illnesses related to HIV/AIDS; (8) develops policy related to both primary prevention of HIV infection and secondary prevention of its severe manifestations based on scientific investigations and clinical trials; (9) provides epidemiologic consultation to State and local health departments, other Public Health Service agencies, universities, and other groups and individuals investigating HIV/AIDS; (10) responds to inquiries from physicians and other health providers for information on the medical and epidemiologic aspects of HIV/AIDS; (11) collaborates internationally with HIV/AIDS researchers and the International Activities Branch in the conduct of epidemiologic studies; and (12) works closely with NCID to determine virologic and immunologic factors related to transmission and natural history of HIV infection.

International Activities Branch (CK53).

(1) Designs and executes epidemiologic and interventional studies of HIV infection and its associated illnesses in other Nations; (2) develops and conducts epidemiologic studies of risk factors for AIDS and HIV transmission in other Nations; (3) assists in the design, implementation, and evaluation of AIDS prevention and control activities; (4) manages international field sites and staff assigned to those sites; (5) in collaboration with NCID, conducts international surveillance and studies of HIV genotypic variants and their epidemiologic and diagnostic implications; (6) provides technical

assistance to other Nations to develop AIDS case surveillance systems; (7) assists foreign governments in carrying out seroprevalence studies and surveys; (8) collaborates with other branches in assisting developing countries in the design, implementation, and evaluation of strategies to protect their blood supplies; (9) coordinates with other CIOs in CDC that have similar international responsibilities; (10) provides consultation to WHO, USAID, and other organizations whose mission is to prevent and control HIV infection and related outcomes; (11) collaborates with national and international organizations to strengthen public health infrastructures at national levels, contributing to technical and managerial sustainability of national HIV prevention and control programs; (12) assist national and international organizations in identifying, developing, and promoting HIV interventions and technologies that are feasible, effective, and culturally appropriate for use in developing countries.

Prevention Services Research Branch (CK54).

(1) Plans, develops, and conducts research to develop and improve HIV prevention strategies and service provision; (2) plans, develops, and coordinates local and regional studies of the determinants of risk for HIV infection in specific populations; (3) plans, develops, and coordinates local and regional studies to identify and evaluate specific at-risk populations, and examines and evaluates prevention service application in these populations; (4) collaborates closely with other NCHSTP and CDC organizations in applying research methods to target, evaluate, and monitor HIV prevention programs in specific geographic settings and at-risk populations; (5) develops and utilizes specific research evaluation and monitoring methodologies including prevalence and incidence studies of HIV and related infections in selected geographic areas and at-risk populations; (6) collects data on the extent of HIV prevalence and incidence in the United States; (7) collaborates with division staff to evaluate HIV/AIDS trends in incidence and prevalence; (8) serves as a focus for national and international activities related to transfusion-related HIV transmission; (9) develops, plans, and conducts studies of HIV counseling and testing activities in a variety of prevention service settings, including but not limited to publicly funded managed care settings; (10) collects and analyzes HIV prevalence and incidence data from publicly funded HIV counseling and

testing sites; (11) assists NCID with the evaluation of new HIV-related tests; (12) conducts local and regional studies of HIV genotypic variations and antiretroviral drug resistance; (13) collaborates with NCID laboratories to develop a repository of stored sera and cells for studies of HIV and related infections.

Statistics and Data Management Branch (CK55). (1) Manages, directs, and coordinates the statistics and data management activities and services for the division and the Division of HIV/AIDS Prevention—Intervention Research and Support (DHAP/IRS); (2) provided leadership in the development of statistical and data management planning, policy, implementation, and evaluation; (3) provides data management and statistical support for HIV/AIDS surveillance, HIV serosurveys, epidemiologic studies and other studies conducted within the division and DHAP/IRS; (4) creates mathematical models to project the incidence of AIDS and HIV infection; (5) develops, monitors, and evaluate projects to construct mathematical models of the spread of AIDS and HIV infection and other HIV and AIDS studies; (6) provides statistical models of epidemiologic parameters to describe the efficiency of HIV transmission and the incubation time for AIDS; (7) responds to inquiries from medical professionals, health departments, the media, and the public about AIDS epidemic statistical issues, including projections of the number of AIDS cases and estimates of person infected with HIV; (8) coordinates contracted programming services for the division.

Surveillance Branch (CK56). (1) Conducts surveillance of HIV infection and AIDS in coordination with State and local health departments to provide population-based data for public health policy development and evaluation; (2) maintains, analyzes, and disseminates information from the national confidential registry of HIV/AIDS cases; (3) monitors HIV-related morbidity and mortality and the use of recommendations for prevention and treatment of HIV infection and AIDS; (4) promotes uses of surveillance data for prevention and evaluation; (5) conducts surveillance of special populations of epidemiologic importance, e.g., persons with HIV-2 infection, health care workers for occupationally related HIV transmission, and person reported with unrecognized modes of transmission; (6) in coordination with State and local health departments, conducts population-based surveillance of HIV-related risk behaviors; (7) assesses socioeconomic, educational, and other

factors of use in targeting and evaluating prevention and care programs; (8) evaluates surveillance systems for HIV infection and AIDS and modifies surveillance methodologies as needed to meet changing needs of HIV/AIDS programs; (9) manages extramural funding of surveillance activities and provides consultations and technical assistance on surveillance activities and methodologies to State and local health departments and national and international organizations and agencies.

Dated: August 24, 1998.

Stephen B. Thacker,

Acting Deputy Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0378]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 1, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223. **SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Color Additive Certification Requests and Recordkeeping—(21 CFR Part 80)—(OMB Control Number 0910-0216)—Extension

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed unsafe unless the additive and its use are in conformity with a regulation that describes the conditions under which the additive may be safely used, or unless the additive and its use conform to the terms of an exemption for investigational use. If a regulation prescribing safe conditions of use has been issued, the additive must be from a batch certified by FDA to conform to the requirements of that regulation and other applicable regulations, unless the additive has been exempted from the certification requirement.

Section 721(c) of the act instructs the Secretary of Health and Human Services (through FDA) to issue regulations providing for batch certification of color additives for which she finds such requirement to be necessary in the interest of protecting the public health. FDA's implementing regulations in 21 CFR part 80 specify the information that must accompany a request for certification of a batch of color additive and require certain records to be kept pending and after certification. FDA requires batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempt from certification.

Under § 80.21, a request for certification must include: Name of color additive, batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), fee, and signature of requestor. The request for certification must also include a sample of the batch of color additive that is the subject of the request. Under § 80.22, the sample must be labeled to show: Name of color additive, batch number and quantity, and name and address of person requesting certification. A copy of the label or labeling to be used for the batch must accompany the sample. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the disposal of all the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The request for certification of a batch of color additive is reviewed by FDA's Office of Cosmetics and Colors to verify