DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–04–0493]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

The National School-based Youth Risk Behavior Survey, OMB No. 0920–0493—Reinstatement with change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The purpose of this request is to renew OMB clearance to continue an ongoing biennial survey among high school students attending regular public, private, and Catholic schools in grades 9–12. Data will be collected in the Spring of 2005 and the Spring of 2007 to assess priority health risk behaviors related to the major preventable causes of mortality, morbidity, and social problems among both youth and adults in the U.S. OMB clearance for the 2003 Youth Risk Behavior Survey (OMB No. 0920–0493) expired November 2003.

Data on the health risk behaviors of adolescents is the focus of approximately 40 national health objectives in Healthy People 2010. The Youth Risk Behavior Survey provides data to measure at least 10 of these health objectives and 3 of the 10 Leading Health Indicators. In addition, the Youth Risk Behavior Survey can identify racial and ethnic disparities in health risk behaviors. No other national source of data measures as many of the 2010 objectives that address behaviors of adolescents. The data will also have significant implications for policy and program development for school health programs nationwide. There are no costs to respondents. The estimated annualized burden over the three-year period is 6,115 hours.

Respondents	Number of respondents (05–07)	Number of responses per respondent	Average burden per response (in hrs)
High School Students	8,000	1	45/60
School Administrators	230	1	30/60

Dated: October 4, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–22713 Filed 10–7–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Competitive Funds for National Programs To Improve the Health, Education, and Well-Being of Young People, Program Announcement Number 04010

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Competitive Funds for National Programs to Improve the Health, Education, and Well-Being of Young People, Program Announcement Number 04010.

Times and Dates: 10 a.m.–10:30 a.m., October 26, 2004 (Open). 10:30 a.m.–12:30 p.m., October 26, 2004 (Closed).

Place: Teleconference Number: 1.888.576.9873 pass code 13503 for the open portion of the meeting.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04010.

Contact Person for More Information: Nosrat Irannejad, MPH, Lead Education Program Specialist, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS–K31, Atlanta, GA 30341, Telephone 770.488.6124.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 1, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–22712 Filed 10–7–04; 8:45 am]

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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 67772–67776, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 69 FR 48247–48249, dated August 9, 2004, is amended to reflect the consolidation of the Centers for Disease Control and Prevention budget execution functions within the Financial Management Office, Office of the Chief Operating Officer.

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

Revise the functional statement for the *Financial Management Office (CAJ2), Office of the Chief Operating Officer (CAJ)* as follows:

Delete in their entirety the title and functional statement for the *Financial Policy and Internal Quality Assurance Activity (CAJ212).*

Delete the functional statement for the *Budget Branch (CAJ23)* and insert the following:

Budget Execution Branch (CAJ23). (1) Promotes structured, ongoing partnerships between the CIOs, FMO leadership, Lead Budget Analysis, and Budget Execution staff; (2) provides leadership, consultation, guidance, and advice on budgetary matters for the CDC through senior advisory leadership roles in partnership with FMO and CIO Directors; (3) provides submission and execution of the CDC budget within the framework of HHS, OMB, Congressional regulations, and policies of the CDC Office of the Director; (4) supports the functions provided by the Budget Oversight and Analysis Activity and Budget Execution Services Activity; (5) provides leadership, consultation, guidance and advice on financial policy and internal quality assurance matters for CDC; (6) develops, analyzes, and evaluates financial management policies, guidelines, and services which have CDC-wide impact; (7) works with personnel from all disciplines within CEC to identify the areas in which financial policy needs to be strengthened; (8) reviews, assesses, and recommends financial policy that is consistent with internal controls and the hierarchy of Federal and Department of Health and Human Services policies and procedures; (9) ensures that resources are safeguarded against fraud, waste, and abuse; managed economically and efficiently; and desired results are achieved; (10) reviews and independently assesses the soundness, adequacy, and application of budgetary and accounting controls; (11) reviews the reliability and integrity of financial and budget information and the means used to identify, measure, classify, and report such information; (12) reviews the adequacy and effectiveness of systems and procedures having an impact on expenditures of funds and use of resources; and (13) assesses the reliability and accuracy of accounting and budgetary data and reports.

Budget Oversight and Analysis Activity (CAJ232). (1) Supports the formulation of CDC's annual budget and provides agency-level and departmental budget execution functions and reporting; (2) oversees budget execution services provided to terrorism and stockpile, global health, and OC/OCOO functions; (3) develops standard operating procedures for budget processes, collaborates with the Chief Learning Officer and Corporate University to develop appropriate training, and provides technical assistance in the interpretation of rules and regulations.

Budget Execution Services Activity (CAJ233). (1) Provides budget execution services to CIOs; (2) coordinates budget services through formalized and integrated communication with CIO programs throughout its service offering to ensure effective and efficiently delivery of services to its customers; (3) supports the formulation of CIO annual budgets, develops spending plans, and manages budget execution activities ensuring funds are expended in accordance with Congressional intent.

Delete item (4) of the functional statement for the *Administrative Services Branch (Spokane) (CC114), Office of Administrative and Management Services (CC11), Office of the Director (CC1), National Institute for Occupational Safety and Health (CC),* and renumber the remaining items accordingly.

Delete item (3) of the functional statement for the *Office of Program Management and Operations (CE13), Office of the Director (CE1), National Center for Injury Prevention and Control (CE),* and insert the following: (3) prepares annual budget formulation and budget justifications.

Delete item (4) of the functional statement for the *Office of the Director (CJ1), National Immunization Program (CJ),* and insert the following: (4) prepares, reviews, and coordinates informational and programmatic documents.

Delete item (4) of the functional statement for the *Planning and Evaluation Office (CK15), Office of the Director (CKI), National Center for HIV, STD, and TB Prevention (CK)*, and renumber the remaining items accordingly.

Delete item (3) of the functional statement for the *Office of the Director (CK61), Global AIDS Program (CK6)*, and insert the following: (3) provides GAP-wide administrative and management services including personnel, contracts, grants and cooperative agreements, and interagency/reimbursable agreements, travel, facility management, and equipment inventory and coordinates or ensures coordination with the appropriate NCHSTP or CDC staff offices.

Delete item (6) of the functional statement for the *Office of the Director (CK61), Global AIDS Program (CK6)*, and renumber the remaining items accordingly.

Delete item (4) of the functional statement for the *Country Program Support (CK63)*, and insert the following: (4) coordinates with BEB/FMO in the development, disbursement, and oversight of country budgets.

Delete item (6) of the functional statement for the *Country Program Support (CK63)* in its entirety.

Delete items (2) and (11) of the functional statement for the *Program Services Branch (CL17), Office of the Director (CL1), National Center for Chronic Disease Prevention and Health Promotion (CL)*, and insert the following: (2) provides leadership, planning, coordination, advice, and guidance in the execution and maintenance of the Center's administrative functions;* * *(11) provides overall programmatic direction for planning and management oversight of allocated resources.

Delete item (5) of the functional statement for the *Office of the Director (CN1), National Center for Environmental Health (CN)*, and insert the following: (5) provides overall programmatic direction for planning and management oversight of allocated resources, human resource management and administrative support.

Delete item (5) of the functional statement for the *Office of Financial and Administrative Services (CN14)*, and insert the following: (5) formulates and provides overall programmatic direction for planning and management oversight of allocated resources, human resource management and administrative support.

Delete item (7) of the functional statement for the *Office of the Director (CR21), Division of Global Migration and Quarantine (CR2), National Center for Infectious Diseases (CR)*, and renumber the remaining items accordingly.

Delete item (6) of the functional statement for the *Office of the Director (CRJ1), Artic Investigations Program (CRJ)*, and insert the following: (6) responsible for budget formulation.

Delete items (1), (6) and (8) of the functional statement for the *Office of Planning, Budget and Legislation (CS17), Office of the Director (CS1), National Center for Health Statistical (CS)*, and insert the following: (1) Provides a focus for short and long range statistic programs, policy development, and program analysis; . . . (6) serves as principal advisor in areas of resource development and budget formulation; * * * (provides overall programmatic oversight of allocated resources.

Dated: September 29, 2004.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04–22603 Filed 10–7–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0441]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for FDA Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit written or electronic comments on the collection of information by December 7, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827 1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for FDA Approval to Market a New Drug— 21 CFR Part 314—(OMB Control Number 0910 0001)—Extension

Under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the act is effective with respect to such drug. Section 505(b) and 505(j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR 314), who apply for approval of a new drug application in order to market or to continue to market a drug.

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application.

Section 314.50(i) requires that patent certification information be submitted in 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that an archival, review, and field copy of the application be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders be sent by 505(b)(2) applicants.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA