DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Statement of Organization, Functions, and Delegations of Authority

Part T (Agency for Toxic Substances and Disease Registry) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (50 FR 25129–25130, dated June 17, 1985, as amended most recently at 69 FR 86–87, dated January 2, 2004, is amended to reflect the consolidation of the Agency for Toxic Substances and Disease Registry budget execution functions within the Financial Management Office, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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

Delete item (5) of the functional statement for the *Office of the Director (TB),* 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 (TB1),* and insert the following: (5) formulates the budget and provides overall programmatic direction for planning and management oversight of allocated resources.

Delete item (1) of the functional statement for the *Program Services Activity (TB612), Office of the Director (TB61), Division of Health Assessment and Consultation (TB6),* and insert the following: (1) Coordiantes the development of the Division's budget and provides overall programmatic direction for planning and management oversight of allocated resources.

The Chief Operating Officer, CDC, has been delegated the authority to sign general **Federal Register** notices for both the CDC and ATSDR.

Dated: September 29, 2004.

William H. Gimson,

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

[FR Doc. 04–22604 Filed 10–8–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–04–0455X]

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

Learning from Principal Investigators of Research Projects Funded through the Extramural Prevention Research Program: How Can CDC Best Support Participatory Research and the Dissemination and Translation of Research Findings? — New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

Two of the current priorities of CDC are to (1) substantially increase CDC's extramural public health research portfolio and budget and (2) develop a more client-oriented or customer-focused approach in all of CDC's activities. As part of its strategy to strengthen and expand extramural public health research, CDC received new money from Congress in 1999 to establish an extramural prevention research program. This program would focus on linking the talents and skills of university-based scientists with the resources of health departments, community-based programs, and national organizations in order to try to better respond to the health needs of individual communities.

Through its first round, the Extramural Prevention Research Program (EPRP), then known as the Prevention Research Initiative, provided $12.5 million in funding annually to support 56 three-year research projects based in states and localities throughout the country. The topics of these research projects were as diverse as asthma, traumatic brain injuries, tobacco control, workplace safety, and health disparities. All of the projects were community-based, and approximately one-third used a participatory approach in which, rather than just having community members be subjects of the research as is the usual case, researchers were to engage members of the community being studied (*i.e.*, those who were expected to be the users of the research findings) in the research process itself. It is believed that engaging the users in the research will make it more likely that the research undertaken will address their actual needs and that they will be more likely to apply the research findings.

Because of this commitment, CDC and many other federal and non-federal funding agencies are very interested in funding participatory research. Yet, anecdotal information and findings from an evaluation project conducted by CDC suggested that funding programs may need to adjust their expectations, requirements, and communication strategies if they want to attract and adequately support the conduct of participatory research projects, and if they want to best support the dissemination and translation into practice of research findings. Therefore, this project will involve conducting one-on-one, semi-structured, open-ended, qualitative interviews with the principal investigators of the grants funded in the first round of the EPRP in order to learn how CDC can best support community-based and participatory research, and how it can best participate in the dissemination and translation of the studies' findings into practice. The approximate annualized burden is 36 hours.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Principal Investigators funded through the first round of the EPRP who self-report that they used a participatory research approach	30	1	45/60

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Principal Investigators funded through the first round of the EPRP who self-report that they did not use a participatory research approach	26	1	30/60

Dated: October 4, 2004.

Alvin Hall,

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

[FR Doc. 04–22819 Filed 10–8–04; 8:45 am]

BILLING CODE 4163–18–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0034]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Current Good Manufacturing Practices Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices; Current Good Manufacturing Practices Quality System Regulation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 14, 2004 (69 FR 33035), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0073. The approval expires on September 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22761 Filed 10–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0103]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Special Protocol Assessment'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 9, 2004 (69 FR 41502), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0470. The approval expires on September 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22762 Filed 10–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0442]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recall Regulations (Guidelines)

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 (the 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 FDA's recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities.

DATES: Submit written or electronic comments on the collection of information by December 13, 2004.

ADDRESSES: Submit electronic comments on the collection of to 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: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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