

Date: July 8, 2010.
Carol Walker,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
[30Day-10-0555]

Agency Forms Undergoing Paperwork Reduction Act Review

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) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of

Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Public Health Performance Standards Program Local Public Health System Assessment (OMB 0920-0555 exp. 8/31/10)—Extension—Office of State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Office of State, Tribal, Local and Territorial Support is proposing to extend the formal, voluntary data collection that assesses the capacity of local public health systems to deliver the essential services of public health. Local health departments will respond to the survey on behalf of the collective body of representatives from the local public health system. Electronic data submission will be used when local public health agencies complete the public health assessment.

A three-year approval is being sought with the current data collection instrument. The data collection instrument has been valuable in assessing performance and capacity and identifying areas for improvement.

From 1998-2002, the National Public Health Performance Standards Program convened workgroups with the National Association of County and City Health Officials (NACCHO), The Association of State and Territorial Health Officials (ASTHO), the National Association of Local Boards of Health (NALBOH), the American Public Health Association (APHA), and the Public Health Foundation (PHF) to develop performance standards for public health systems based on the essential services of public health. In 2005, CDC reconvened workgroups with these same organizations to revise the data collection instruments, in order to ensure the standards remain current and improve user friendliness. There is no cost to the respondent, other than their time. The estimated annualized burden hours are 5600.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Local Public Health System	Local Public Health System Performance Assessment Instrument.	350	1	16

Dated: July 9, 2010.
Thelma Sims,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
[30-Day-10-10DT]

Agency Forms Undergoing Paperwork Reduction Act Review

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Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Monitoring and Reporting System for Chronic Disease Prevention and Control Programs—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. The Centers for Disease Control and Prevention (CDC) works with states, territories, tribal organizations, and the District of Columbia (collectively referred to as “state-based” programs) to develop, implement, manage, and evaluate chronic disease prevention and control programs. Support and guidance for these programs have been provided through cooperative agreement funding and technical assistance, administered

by CDC’s National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Partnerships and collaboration with other Federal agencies, nongovernmental organizations, local communities, public and private sector organizations, and major voluntary associations have been critical to the success of these efforts.

CDC seeks OMB approval for three years to collect progress and activity information from health departments funded for four program areas: Tobacco control, diabetes prevention and control, Healthy Communities, and state-based behavioral risk factor surveillance. Information will be collected electronically through a new, electronic Management Information System (MIS). Information will be collected on each program area’s objectives, planning activities, resources, partnerships, policy and environmental strategies for preventing or controlling chronic diseases, and progress toward meeting goals. The new MIS harmonizes the progress reporting framework for all program areas and

will support the collection of accurate, reliable, uniform and timely information. The MIS will generate a variety of routine and customizable reports that will allow each State or program to summarize its activities and progress. CDC will also have the capacity to generate reports that describe activities across multiple States and/or programs. The new MIS will replace two previously approved systems used by tobacco control programs (OMB No. 0920-0601, exp. 5/31/2010) and diabetes prevention and control programs (OMB No. 0920-0479,

exp. 4/30/2013), which are being phased out.

CDC will use the information collection to monitor each program's progress and use of federal funds, to identify strengths and weaknesses, to make adjustments in the type and level of technical assistance provided to programs, and to respond to inquiries. Respondents will use the information collection to manage and coordinate their activities and to improve their efforts to prevent and control chronic diseases.

The initial set of respondents will be health departments in all 50 states, the

District of Columbia, Puerto Rico, and the U.S. Virgin Islands. All awardees will report on tobacco control, diabetes prevention and control, behavioral risk factor surveillance, and Healthy Communities, with the exception of the District of Columbia, which is not currently participating in Healthy Communities.

Information will be collected electronically twice per year. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,532.

ESTIMATED ANNUALIZED BURDEN TO RESPONDENTS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Diabetes Program	53	2	6
State Tobacco Program	53	2	6
State BRFSS Program	53	2	6
State Healthy Communities Program	52	2	6

Dated: July 9, 2010.

Thelma Sims,

Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0296]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by August 16, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0381. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400W, Rockville, MD 20850, 301-796-3794, JonnaLynn.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling Regulations—21 CFR Parts 101, 102, 104, and 105 (OMB Control Number 0910-0381)—Extension

FDA regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. FDA's food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under

the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the act and the FPLA.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its