

6 MONTHS ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Number of respondents	Number of responses/ respondent	Average burden hours per response	Total burden hours
Hospital staff (data collection)	6000	96	1	576,000
State/Territory Preparedness staff (training)	62	1	1	62
State/Territory Preparedness staff (data collection)	62	288	3	53,568
Total	386	635,630

The burden was determined by asking the States that participated in a pilot study to report who collected the data and how long it took them to gather the information.

Terry Nicolosi,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0030]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Investigational New Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Investigational New Drug Regulations” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Elizabeth.Berbakos@fda.hhs.gov, 301–796–3792.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 8, 2009 (74 FR 21690), 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 0910–0014. The approval expires on August 31, 2011. A copy of the supporting statement for this

information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: August 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–09AA]

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 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

BioSense—Recruitment of Data Sources—Existing Data Collection Without an OMB Number—National Center for Public Health Informatics (NCPHI), *Coordinating Center for Health Information and Service (CCHIS)*, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires specific activities related to bioterrorism preparedness and response. This congressional mandate outlines the need for improving the overall public's health through electronic surveillance.

The Department of Health and Human Services outlined strategies aimed at achieving this goal via the Public Health IT Initiative thereby creating the BioSense program.

BioSense is a national, human health surveillance system designed to improve the nation's capabilities for disease detection, monitoring, and real-time health situational awareness. This work is enhanced by providing public health real-time access to existing data from healthcare organizations, state syndromic surveillance systems, national laboratories, and others for just in time public health decisionmaking; this information is made available to users in the BioSense Application. The application provides data, charts, graphs, and maps through a secure Web-based interface which can be accessed by CDC and authorized users from state and local public health departments and healthcare organizations.

In order to meet the congressional mandate, the BioSense program must have access to electronic health data. Recruitment of data sources includes collecting information on the types of data available, the types of computer systems used, and the approximate record volume. This information is used by BioSense personnel and contractors to determine technical requirements for linking a data source into the BioSense program. To collect this information, a series of questionnaires in an Excel spreadsheet have been designed. Information collection will take place during and after on-site visits by BioSense personnel and contractors. We estimate that such information will be collected from 20 new entities (each representing many facilities or clinics) each year.

Since the publication of the 60-day **Federal Register** Notice, the information collection instrument for the provision of access to the BioSense Application has been included in this information collection request. Access to the BioSense Application is obtained using an automated data collection form. This form is completed on the Internet via the CDC Secure Data Network (SDN) in which a prospective user identifies what