LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–0728]

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 (404) 639–7570 or send an email 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 Notifiable Disease Surveillance System (NNDSS) [*0920–0728,* Exp, Jan 31, 2014]—Revision—Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Division of Health Informatics and Surveillance (DHIS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The Nationally Notifiable Disease Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These *reportable conditions,* which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Currently approximately 300 conditions are reportable in one or more of the states. Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments have to be able to share data on certain conditions across jurisdictions and coordinate program activities to prevent and control the conditions. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, performs an assessment of conditions reported to state, territorial and local jurisdictions to determine which should be designated *nationally notifiable conditions.* For conditions that are nationally notifiable, case notifications are voluntarily submitted to CDC so that information can be shared across jurisdictional boundaries and both surveillance and prevention and control activities can be coordinated at regional and national levels.

CDC requests a three year approval for a Revision of the National Notifiable Diseases Surveillance System (NNDSS) information collection, [National Electronic Disease Surveillance System (NEDSS, OMB Control No. *0920–0728,* Expiration Date 01/31/2014]. This request has been developed in coordination with four other CDC applications to OMB for nationally notifiable diseases case notification: Control Numbers 0920–0128, (Congenital Syphilis Surveillance), *0920–0819* (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance) *0920–0009* (National Disease Surveillance Program—I. Case Reports) and *0920–0004* (National Disease Surveillance Program—II. Disease Summaries). This consolidation of information collection 0920–0128 and some parts of information collections 0920–0819, 0920–0009 and 0920–0004, is an important step in implementing CDC's longer term strategy of developing a more coordinated and integrated infectious diseases surveillance system that reduces overlap and duplication; increases interoperability, integration and efficiency; and thereby reduces burden to state, territorial and local health departments that report infectious disease data to CDC. Due to the coordination, this NNDSS application includes 11 conditions and many additional data elements for the case notifications that were not previously included in NNDSS OMB application Control No. *0920–0728.* For many conditions submitted to CDC, participating public health departments also submit data elements which are specific to each condition. With the coordination with other CDC programs conducting surveillance on notifiable conditions, this application includes disease-specific tables for 68 diseases. The 2010 NNDSS OMB application included disease-specific data elements for only 14 of those conditions.

Because this information collection request includes case notifications that were not part of the 2010 NNDSS/NEDSS application, replaces one application and replaces parts of three other OMB applications, burden estimates have been adjusted to incorporate burden estimates from the other four applications. The estimates are adjusted for the increased number of conditions reported to NNDSS, the expansion of core data elements, and the inclusion of more disease-specific tables. These changes have increased the burden estimates in this application in comparison with the burden estimates in the 2010 NNDSS/NEDSS OMB application (OMB Control No. *0920–0728).* As CDC works with state, territorial and local health departments to develop and implement new information technologies to submit these data through NNDSS, burden will also increase as the public health departments commit resources to implementing the new technologies. However, over the next 3 years, as the new automated electronic systems are implemented, burden will be decreased. There are no costs to respondents other than their time. The estimated annual burden is 28,340 hours.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
States	50	52	10
Territories	5	52	5
Cities	2	52	10

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Performance Review Board Members

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members who are reviewing performance for Fiscal Year 2013.

FOR FURTHER INFORMATION CONTACT: Sharon O'Brien, Deputy Director, Executive and Scientific Resources Office, Human Capital and Resources Management Office, Centers for Disease Control and Prevention, 4770 Buford Highway NE., Mailstop K–15, Atlanta, Georgia 30341, Telephone (770) 488–1781.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following persons will serve on the CDC Performance Review Boards or Panels, which will oversee the evaluation of performance appraisals of Senior Executive Service members for the Fiscal Year 2013 review period:

Christine Branche, Co-Chair
James Seligman, Co-Chair
Barbara Bowman
Janet Collins
Hazel Dean
Jane Gentleman
Joseph Henderson
Jennifer Parker
Tanja Popovic
Steve Redd
Tom Sinks
Kevin Smagh

Dated: November 8, 2013.

Stacey Hoffman,

Acting Director, Division of Executive Secretariat, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1394]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Special Protocol Assessment

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 the information collection in the guidance for industry on special protocol assessment.

DATES: Submit either electronic or written comments on the collection of information by January 17, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Guidance for Industry on Special Protocol Assessment—(OMB Control Number 0910–0470)—Extension

The ''Guidance for Industry on Special Protocol Assessment'' describes Agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the Agency to act on such requests. The guidance provides information on how the Agency interprets and applies provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes the following two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol and (2) the submission of a request for special protocol assessment.

Notification for a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in Agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days