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[FR Doc. 2013-27485 Filed 11-15-13; 8:45 am]

BILLING CODE 4163-18-P

**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 (CELS), 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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[FR Doc. 2013-27447 Filed 11-15-13; 8:45 am]

BILLING CODE 4163-18-P

**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.

[FR Doc. 2013-27501 Filed 11-15-13; 8:45 am]

BILLING CODE 4163-18-P

**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](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