monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on minority populations and rare cancers. In addition, data on stage at diagnosis, type of treatment provided, and vital status allow CDC to assess progress in reducing morbidity and mortality from cancer. These activities and analyses further support CDC's planning and evaluation efforts for state and national cancer control and prevention. Finally, datasets compiled through the NPCR CSS have been made available to investigators for secondary analysis.

CDC plans to request OMB approval to reinstate the NPCR CSS information collection, with changes. First, the frequency of reporting to CDC will be changed from an annual to a semi-annual schedule. The additional report will allow CDC to compile preliminary cancer incidence estimates in advance of the lengthy process of data validation required for each registry's final annual report. Second, data definitions for each report will be updated to reflect changes in national standards for cancer diagnosis, treatment, and coding. These changes will affect the standard reports for all NPCR-funded central cancer registries.

The third set of changes applies to a subset of 10 central cancer registries. These CCR received ARRA funding to develop common standards and reporting mechanisms for enhanced description of cases of breast cancer, colorectal cancer, and chronic myelogenous leukemia (CML). The enhanced data items will support more in-depth analysis of treatment strategies and patient outcomes than is currently possible with the standard NPCR CSS information collection. The 10 registries that participated in the enhancement process will begin reporting the additional data items to CDC in 2013 as part of their routine submission. CDC plans to make de-identified data available for comparative effectiveness research (CER).

OMB approval will be requested for three years. Respondents will be NPCR-supported central cancer registries in U.S. states, territories, and the District of Columbia. Information will be reported electronically to CDC twice per year. The first report will consist of a single-year file for data that includes diagnoses 12 months past the close of the diagnosis year. The second report will consist of a cumulative file containing incidence data from the first diagnosis year for which the cancer registry collected data with the assistance of NPCR funds (e.g., 1995) through 24 months past the close of the diagnosis year (e.g., 2010 data submitted in 2012). The estimated burden per response is two hours. Because cancer incidence data are already collected, aggregated and used for analyses at the state level, the additional burden of reporting the information to CDC is small and the number of data items in the report does not affect the estimated burden per response. There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Central Cancer Registries in States, Territories, and the District of Columbia.	Standard NPCR CSS Report	38	2	2	152
	Enhanced NPCR CSS Report	10	2	2	40
Total					192

Dated: December 4, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–29722 Filed 12–7–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13–0128]

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

Proposed Project

Congenital Syphilis Case Investigation and Reporting Form (CDC73.126), OMB 0920–0128, Expiration 03/31/2013—Revision—National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Congenital syphilis (CS) is an important sentinel health event that marks potential problems in both prenatal care and syphilis prevention programs. Congenital syphilis (CS) is nearly 100% preventable by early detection and treatment of syphilis in pregnant women before or during pregnancy.

Reducing congenital syphilis is a national objective in the U.S. Department of Health and Human Services report entitled, ''Healthy People 2020''.

The CDC continues to collect and report information on congenital syphilis morbidity as part of its ongoing Sexually Transmitted Disease (STD) surveillance efforts. A reporting form for congenital syphilis (CDC Form 73.126) was initiated in 1983 to improve detection, case management, and treatment of congenital syphilis cases. Continued data collection will assist in identifying needs for congenital syphilis prevention efforts nationwide.

The current CS reporting form was revised and approved by OMB in 2009 to collect information based on the surveillance case definition and removal of Reporting city information. It is being used by all health jurisdictions reporting CS to CDC as part of the National Notifiable Diseases Surveillance. For the new approval period, CDC requests elimination of the

field ''Did the infant/child have an IgM-specific treponemal test?'' This data element is no longer required because treponemal IgM technologies, for the purpose of identifying CS in an infant, are highly insensitive. CDC also requests elimination of infant gender because gender does not influence the case definition or define risk. The following fields have been added: ''Mothers obstetric history'', ''Did mother have treponemal test result: If so, when was the test performed?'' ''What stage of syphilis did mother have?'', ''Date of Mother's treatment'', ''What was mother's treatment?'' ''What clinical and what surveillance stage of syphilis did the mother have during pregnancy'' ''Presumptive has been replaced with probable,'' as there is no case definition for presumptive congenital syphilis and, ''Mother's HIV status during pregnancy''.

The congenital syphilis data will continue to be used to develop intervention strategies and to evaluate ongoing control efforts. There is no cost to respondents other than their time. The total estimated annual burden hours are 62.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Types of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Health Departments	Congenital Syphilis (CS) Case Investigation and Report.	10	11	20/60
Territorial Health Agencies	Congenital Syphilis (CS) Case Investigation and Report.	3	11	20/60
City and county health departments	Congenital Syphilis (CS) Case Investigation and Report.	4	11	20/60

Dated: December 4, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–29723 Filed 12–7–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 10, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 204042, canagliflozin tablets, proposed trade name INVOCANA, submitted by Janssen Research and Development, LLC. Canagliflozin is a member of the sodium-glucose co-transporter 2 (SGLT2) inhibitors, and was developed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 27, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 20, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 21, 2012.

Persons attending FDA's advisory committee meetings are advised that the