ESTIMATE ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Key informant interview respondents	Interview guide	6	1	30/60	3
Focus group respondents	Moderator guide	14	1	2	28
Intercept respondents	Intercept script	40	1	30/60	20
Telephone survey respondents	Survey	1,000	1	27/60	450
Total					501

Ron A. Otten,

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

[FR Doc. 2013–08911 Filed 4–16–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–13–0469]

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) 639–7570 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) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

National Program of Cancer Registries Cancer Surveillance System—(0920–0469 Reinstatement Exp. 11/30/2012)—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1992, Congress passed the Cancer Registries Amendment Act, which established the National Program of Cancer Registries (NPCR). The NPCR provides support for central cancer registries (CCR) that collect, manage and analyze data about cancer cases. The NPCR-funded CCR, which are located in states, the District of Columbia, and U.S. territories, report information to CDC annually through the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS)(OMB No. 0920–0469, exp. 1/31/2010). Many registries maintain additional data items that are not part of the standard NPCR CSS report to CDC.

The NPCR CSS has allowed CDC to collect, aggregate, evaluate and disseminate cancer incidence data at the national and state level, and is the primary source of information for *United States Cancer Statistics* (*USCS*), which CDC has published annually since 2002. The NPCR CSS also allows CDC to monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on minority populations and rare cancers. 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 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. 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.

OMB approval will be requested for three years. Respondents will be 48 NPCR-supported central cancer registries in the U.S. (45 states, the District of Columbia, Puerto Rico, and the Pacific Islands jurisdictions). Information will be reported electronically to CDC twice per year. The first report will consist of a single-year file for data that includes diagnosis 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 modest 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. The total estimated annualized burden hours are 192.

ESTIMATED ANNUALIZED BURDEN HOURS

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

Ron A. Otten,

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

[FR Doc. 2013–08912 Filed 4–16–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0867]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study on the Public Display of Lists of Harmful and Potential Harmful Tobacco Constituents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Experimental Study on the Public Display of Lists of Harmful and Potential Harmful Tobacco Constituents'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On May 8, 2012, the Agency submitted a proposed collection of information entitled ''Experimental Study on the Public Display of Lists of Harmful and Potential Harmful Tobacco Constituents'' 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 0910–0736. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: April 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08906 Filed 4–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0104]

Guidance for Industry on Non-Penicillin Beta-Lactam Drugs: A Current Good Manufacturing Practices Framework for Preventing Cross-Contamination; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' This guidance describes the importance of implementing controls to prevent cross-contamination of finished pharmaceuticals and active pharmaceutical ingredients (APIs) with non-penicillin beta-lactams. This guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitizing beta-lactams (including both penicillins and non-penicillin beta-lactams), beta-lactamase inhibitors, and beta-lactam intermediates and derivatives. Finally, this guidance clarifies that manufacturers should generally utilize separate facilities for manufacture of non-penicillin beta-lactams because those compounds pose health risks associated with cross-reactivity.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula Katz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4314, Silver Spring, MD 20993–0002, 301–796–6972.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' This guidance describes the importance of implementing controls to prevent cross-contamination of finished pharmaceuticals and APIs with non-penicillin beta-lactam drugs. This guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitizing beta-lactams (including both penicillins and non-penicillin beta-lactams). Finally, this guidance clarifies that manufacturers should generally utilize separate facilities for manufacture of non-penicillin beta-lactams because those compounds pose health risks associated with cross-reactivity.

Although the existing current good manufacturing practices (CGMP) regulations require separation of manufacturing facilities to avoid cross-contamination, the only class of products for which the regulations specify particular separation