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

requirements are penicillins. This guidance explains that, due to the potential health risks of cross-contamination, the Agency expects separation for all classes of beta-lactam drugs, including penicillins as well as non-penicillin beta-lactams. Specifically, FDA recommends that manufacturers establish appropriate separation and control systems designed to prevent two types of contamination: (1) The contamination of a non-penicillin beta-lactam by any other non-penicillin beta-lactam and (2) the contamination of any other type of product by a non-penicillin beta-lactam. Accordingly, FDA recommends that the area in which any class of sensitizing beta-lactam is manufactured should be separated from areas in which any other products are manufactured, and should have an independent air handling system.

A draft version of this guidance was published in March 2011 as ''Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework.'' This final version was revised in response to docket comments to clarify that this guidance does not provide a formal risk assessment, but, rather, describes FDA's expectations and recommendations for separation strategies to prevent cross-contamination.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: April 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08913 Filed 4–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Health Care and Other Facilities (OMB No. 0915–0309)—Extension

Abstract: The Health Resources and Services Administration's Health Care and Other Facilities (HCOF) program provides congressionally-directed funds to health-related facilities for construction related activities and/or capital equipment purchases. Awarded facilities are required to provide a periodic (quarterly for construction related projects, annually for equipment only projects) update of the status of the funded project until it is completed. The monitoring period averages about three years, although some projects take up to five years to complete. The information collected from these updates is vital to program management staff to determine whether projects are progressing according to the established timeframes, meeting deadlines established in the Notice of Award, and drawing down funds appropriately. The data collected from the updates is also shared with the Division of Grants Management Operations for their assistance in the overall evaluation of each project's progress.

An electronic form is currently being used for progress reporting for the HCOF program. This form provides awardees access to directly input the required status update information in a timely, consistent, and uniform manner. The electronic form minimizes burden to respondents and informs respondents when there are missing data elements prior to submission. We acknowledge a change in the burden estimate due to close out of old projects.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows: