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:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Construction Related	200	4	800	.5	400
Equipment Only	317	1	317	.5	158.5
Total	517		1,117		558.5

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: April 10, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–09026 Filed 4–16–13; 8:45 am]

BILLING CODE 4165–15–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: Data Collection Tool for State Offices of Rural Health Grant Program. (OMB No. 0915–0322)—Extension

Abstract: The mission of the Office of Rural Health Policy (ORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Section 711 of the Social Security Act [42 U.S.C. 912]), Congress charged ORHP with administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.

In accordance with the Public Health Service Act, Section 338J (42 U.S.C. 254r), the Health Resources and Services Administration proposes to revise the State Offices of Rural Health Grant Program—Funding Opportunity Announcement (FOA) and Forms for the Application. The FOA is used annually by 50 states in preparing applications for Grants under the State Offices of Rural Health Grant Program (SORH) of the Public Health Service Act, and in preparing the required report.

ORHP seeks to continue gathering information from grantees on their efforts to provide technical assistance to clients within their state. SORH grantees would be required to submit a Technical Assistance Report that includes: (1) The total number of technical assistance encounters provided directly by the grantee; and, (2) the total number of unduplicated clients that received direct technical assistance from the grantee. Submission of the Technical Assistance Report would be done via submission to the HRSA Electronic Handbook no later than 30 days after the end of each twelve month budget period.

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:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Technical Assistance Report	50	1	50	12.5	625
Total	50	1	50	12.5	625

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.