polymorphs, which generally speaking contain only the API within the crystal lattice, co-crystals are composed of an API with a neutral guest compound in the crystal lattice. Similarly, unlike salts, where the components in the crystal lattice are in an ionized state, a co-crystal's components are in a neutral state and interact via nonionic interactions.

At present, no formal regulatory policy exists governing the classification of pharmaceutical co-crystals. In response to this need for regulatory guidance, the guidance provides the Agency's current thinking on the appropriate classification of co-crystal solid-state forms.

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 regulatory classification of pharmaceutical co-crystals. 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. This guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.50(d)(1) and 314.94(a)(5) and 314.94(a)(9) have been approved under OMB control number 0910–0001. The collections of information in the current good manufacturing practice (CGMP) regulations (21 CFR part 211) have been approved under OMB control number 0910–0139.

IV. 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 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09872 Filed 4–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: Medicare Rural Hospital Flexibility Grant Program Performance Measure Determination (OMB No. 0915–xxxx)—New

Abstract: The purpose of the Medicare Rural Hospital Flexibility Program (Flex), authorized by Section 4201 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33 and reauthorized by Section 121 of the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275, is to support improvements in the quality of health care provided in communities served by Critical Access Hospitals (CAHs); to support efforts to improve the financial and operational performance of the CAHs; and to support communities in developing collaborative regional and local delivery systems. Additionally, the Flex program assists in the conversion of qualified small rural hospitals to CAH status. The provision and delivery of quality health care to rural America is a priority of the Department of Health and Human Services (HHS). The Flex program provides funding for states to support technical assistance activities in hospitals related to: improving health care quality, patient safety, hospital financial and operational efficiency, and care coordination; and ensuring adequate training and support within rural Emergency Medical Services systems. Measures and goals identified in the Flex program take into consideration existing measures and priorities HHS has set for hospitals, to avoid both conflict and duplication of efforts.

For this program, performance measures were drafted to provide data useful to the Flex program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62). These measures cover principal topic areas of interest to the Office of Rural Health Policy, including: (a) Quality reporting; (b) quality improvement interventions; (c) financial and operational improvement initiatives; and (d) multi-hospital patient safety initiatives. Several measures will be used for this program and will inform the Office's progress toward meeting the goals set in GPRA.

This notice is the second of two **Federal Register** Notices issued regarding the intent to collect program performance measures, and the Office of Rural Health Policy received one set of comments for the original 60-day notice published on December 31, 2012 (Vol. 77, No. 250, pp. 77079–77080). The Office of Rural Policy responded to the comments and adjusted the burden estimate based on new calculations.

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 ICR are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Medicare Rural Hospital Flexibility Grant Program	45	1	45	216	9,720
Total	45	1	45	216	9,720

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: April 22, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–09946 Filed 4–25–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Award to Genesee Health System.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) funds originally awarded to the County of Genesee to ensure the provision of critical primary health care services to underserved populations in Genesee County, Michigan.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: County of Genesee.

Original Period of Grant Support: June 1, 2012, to April 30, 2014.

Replacement Awardee: Genesee Health System.

Amount of Replacement Award: The original award to the County of Genesee was issued as a result of a New Access Point application. The County of Genesee and Genesee Health System have agreed that the funds to be transferred will be the remaining amount in the account as of the date of this transfer.

Period of Replacement Award: The period of support for the replacement award is May 1, 2013, to April 30, 2014.

Authority: Sections 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.224.

Justification for the Exception to Competition: The former grantee, the County of Genesee, has requested that HRSA transfer a Health Center Program section 330 grant to Genesee Health System to implement and carry out grant activities originally proposed under the County of Genesee's funded section 330 grant application. Genesee County Community Mental Health (GCCMH)—now Genesee Health System—was formerly a department of the County of Genesee and has continued to carry out the operations of the grant program since its award in June 2012. On January 1, 2013, the State of Michigan approved GCCMH's independence as a separate public governmental entity, and GCCMH was legally renamed the Genesee Health System. The Genesee Health System is directly engaged in the delivery of primary health care services on the County of Genesee's behalf and has indicated an ability to continue operations without a disruption of services.

Genesee Health System is currently providing primary health care services on behalf of the County of Genesee to the original target population and is located in the same geographical area. This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay or disruption of services caused by a competition. As a result, in order to ensure that critical primary health care services remain available to the original target population without disruption, this replacement award will not be competed.

FOR FURTHER INFORMATION CONTACT: Kirsten Argueta, Senior Advisor, North Central Division, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857, via email at *KArgueta@hrsa.gov* or (301) 594–1055.

Dated: April 19, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–09942 Filed 4–25–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Zirconium-89 PET Imaging Agent for Cancer

Description of Technology: This technology is a new generation of rationally designed chelating agents which improve the complexation of Zirconium-89 for PET imaging of cancers. The technology uses cyclic or acyclic chelators made of 4 hydroxamate donors groups for improved stability compared to the currently used natural product siderophore desferrioxamine B (DFB), a