5. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Use:* The Chief Financial Officers (CFO) Act of 1990, as amended by the Government Management Reform Act (GMRA) of 1994, requires government agencies to produce auditable financial statements. Because the Centers for Medicare & Medicaid Services (CMS) fulfills its mission through its contractors and the States; these entities are the primary source of information for the financial statements. There are three basic categories of data: Expenses, payables, and receivables. The CMS–64 is used to collect data on Medicaid expenses. The CMS–R–199 collects Medicaid payable and receivable accounting data from the States. *Form Number:* CMS–R–199 (OCN: 0938–0697); Frequency: Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 336. (For policy questions regarding this collection contact Michele Myers at 410–786–7911. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 28, 2013.* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov*.

Dated: April 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–09913 Filed 4–25–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0800]

Guidance for Industry on Regulatory Classification of Pharmaceutical Co-Crystals; 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 ''Regulatory Classification of Pharmaceutical Co-Crystals.'' This guidance provides applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) with the Center for Drug Evaluation and Research's (CDER's) current thinking on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data the applicant should submit to support the appropriate classification of a co-crystal, as well as the regulatory implications of the classification.

The recommendations in this guidance apply to materials that the Agency has not previously evaluated and determined to be pharmaceutical co-crystals. The recommendations do not apply to materials that the Agency has previously designated as salts, complexes, or other non-co-crystalline forms.

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:

Andre Raw, Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Pl., Rockville, MD 20855, 240–276–8500; or

Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, rm. 1626, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–1900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Regulatory Classification of Pharmaceutical Co-Crystals.'' This guidance provides applicants of NDAs and ANDAs with CDER's current thinking on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data the applicant should submit to support the appropriate classification of a co-crystal, as well as the regulatory implications of the classification.

On December 2, 2011 (76 FR 75551), FDA announced the availability of the draft version of this guidance. The public comment period closed on March 1, 2012. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

Co-crystals are solids that are crystalline materials composed of two or more molecules in the same crystal lattice. These solid-state forms, composed of an active pharmaceutical ingredient (API) with a neutral guest compound (also referred to as a conformer), have been the focus of significant interest in drug product development. Pharmaceutical co-crystals have opened the opportunity for engineering solid-state forms designed to have tailored properties to enhance drug product bioavailability and stability, as well as enhance processability of the solid material inputs in drug product manufacture. Pharmaceutical co-crystals are of interest because they offer the advantage of generating a diverse array of solid-state forms from APIs that lack ionizable functional groups needed for salt formation.

Traditionally, solid-state polymorphic forms of an API are classified as either crystalline, amorphous, or solvate and hydrate forms, and applicable regulatory schemes for these solid-state polymorphic forms are well-defined. Co-crystals, however, are distinguishable from these traditional pharmaceutical solid-state forms. Unlike

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.