of Offeror, requires each offeror to identify if the offeror is, within the last three years, a successor to another entity that received a Federal Government award and, if so, to provide the Commercial and Government Entity (CAGE) code and legal name of the predecessor. The information on predecessors is used to identify such entities in the Federal Awardee Performance and Integrity Information System (FAPIIS) to allow retrieval of integrity and performance data on the most recent predecessor of an apparent successful offeror to whom award is anticipated. FAR 9.104–6 requires contracting officers to consult FAPIIS before awarding a contract in excess of the simplified acquisition threshold. The information on predecessors is collected on an annual basis for inclusion in the annual representations and certifications in the System for Award Management (SAM) for offerors required to register in SAM. Offerors not required to register in SAM but required to provide the information in the provision at FAR 52.204–20 will do so as specified in the solicitation or instructed by the contracting officer.

C. Annual Reporting Burden

The burden to provide the information required by the FAR provision at 52.204–20 when an offeror is registered in SAM is already covered by OMB Control Number 9000–0159, System for Award Management Registration (SAM). OMB Control Number 9000–0189 now will cover the burden for providing the required information when the offeror is not required to register in SAM in accordance with the exceptions in FAR 4.1102(a). The Federal Procurement Data System (FPDS) for FY 2017 was used to develop the estimated burden hours as shown below:

Respondents: 974.

Responses Per Respondent: 1.

Total Annual Responses: 974.

Hours Per Response: 0.1.

Total Burden Hours: 97.4.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0189, Identification of Predecessors, in all correspondence.

Dated: September 13, 2018.

William Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2018–20299 Filed 9–18–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10673]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 19, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration; *Use:* The Centers for Medicare & Medicaid Services (CMS) may test a demonstration, under Section 402 of the Social Security Amendments of 1968 (as amended), entitled the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration (''the Demonstration''). If it goes forward, the MAQI demonstration could test whether exempting, through the use of waiver authority, clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) (combined with participation, if any, in Advanced Alternative Payment Models (APMs) with Medicare Fee-for-Service (FFS)) from the Merit-based Incentive Payment System (MIPS) reporting requirements

and payment adjustment will increase or maintain participation in payment arrangements with MAOs similar to Advanced APMs and change the manner in which clinicians deliver care.

Clinicians may currently participate in one of two paths of the Quality Payment Program (QPP): (1) MIPS, which adjusts Medicare payments based on combined performance on measures of quality, cost, improvement activities, and advancing care information, or (2) Advanced Alternative Payment Models with Medicare (Advanced APMs), under which eligible clinicians may earn an incentive payment for sufficient participation in certain payment arrangements with Medicare fee-for-service (FFS) and other payers, and starting in the 2019 performance period, with other payers such as Medicare Advantage, commercial payers, and Medicaid managed care. To participate in the Advanced APM path of QPP for a given year, eligible clinicians must meet the criteria of Qualifying APM Participants (QPs); in addition to earning an APM incentive payment, QPs are excluded from the MIPS reporting requirements and payment adjustment.

An eligible clinician that does not meet the criteria to be a QP for a given year will be subject to MIPS for that year unless the clinician meets certain other MIPS exclusion criteria, such as being newly enrolled in Medicare or meeting the low volume threshold for Medicare FFS patients. The MAQI Demonstration could allow participating clinicians to have the opportunity to be exempt from MIPS reporting and payment consequences for a given year if they participate to a sufficient degree in certain Qualifying Payment Arrangements with MAOs (and Advanced APMs with Medicare FFS) during the performance period for that year, without requiring them to be QPs or otherwise meet the MIPS exclusion criteria of QPP. Under a possible Demonstration, clinicians might not be required to have a minimum amount of participation in an Advanced APM with Medicare FFS in order to be exempt from MIPS reporting requirements and payment adjustments for a year, but if they did have participation in Advanced APMs with Medicare FFS, that participation could also be counted towards the thresholds that trigger the waiver from MIPS reporting and payment consequences. In addition, the Demonstration could permit consideration of participation in ''Qualifying Payment Arrangements'' with Medicare Advantage plans that meet the criteria to be Other Payer Advanced APMs a year before the All-Payer Combination Option is available.

In the Calendar Year 2018 Quality Payment Program Final Rule, CMS noted its intention ''to develop a demonstration project to test the effects of expanding incentives for eligible clinicians to participate in innovative alternative payment arrangements under Medicare Advantage that qualify as Advanced APMs, by allowing credit for participation in such Medicare Advantage arrangements prior to 2019 and incentivizing participation in such arrangements in 2018 through 2024.'' (92 FR 53865).

The first performance period for the Demonstration is tentatively planned for 2018 and the Demonstration would last up to five years. Clinicians who meet the definition of MIPS eligible clinician under QPP as defined under 42 CFR 414.1305 would be eligible to participate in the MAQI Demonstration. Currently, MIPS eligible clinicians include physicians (including doctors of medicine, doctors of osteopathy, osteopathic practitioners, doctors of dental surgery, doctors of dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. If the definition of MIPS eligible clinician changes under future rulemaking, the Demonstration would use the updated definition to define Demonstration eligibility.

Participation could last the duration of the Demonstration, unless participation is voluntarily or involuntarily terminated under the terms and conditions of the Demonstration. Participants would have the opportunity to submit the required documentation and be evaluated for MIPS waivers through the Demonstration each year.

Should this demonstration move forward, and in order to conduct an evaluation and effectively implement the MAQI Demonstration, CMS would need to collect information from Demonstration participants on (a) payment arrangements with MAOs and (b) Medicare Advantage (MA) payments and patient counts. CMS would require a new collection of this information as this information is not already available through other sources and/or has not been previously approved for use under the MAQI Demonstration. The information collected in these forms would allow CMS to evaluate whether the payment arrangement that clinicians have with MAOs meet the Qualifying Payment Arrangement criteria, and determine whether a clinician's MAO and FFS APM patient population or payments meet demonstration thresholds. Both of these areas are also requirements for review and data collection under QPP (*i.e.* the Eligible Clinician-Initiated Other Payer Advanced APM Determination form and All-Payer QP Submission form), and therefore similar to forms have been prepared and reviewed under the QPP.

Given these similarities in forms, burden estimates for the MAQI Demonstration PRA package were derived from burden analyses and formulation done in conjunction with the QPP forms; more specifically the estimated burden associated with the submission of payment arrangement information for Other Payer Advanced APM Determinations: Eligible Clinician-Initiated Process, and the estimated burden associated with the submission of data for All-Payer QP determinations. CMS estimates the total hour burden per respondent for the MAQI demonstration to be 15 hours, to match the hours listed in the equivalent QPP forms. Full detail of how these estimates were derived can be found in the forthcoming Calendar Year 2019 Proposed QPP rule.

If Demonstration participants submitted information, but did not meet these conditions of the Demonstration, their participation in the Demonstration would not be terminated, but they would not receive the waivers from MIPS reporting requirements and payment adjustments. Therefore, unless they become QPs or are excluded from MIPS for other reasons, the participating clinicians would be subject to MIPS and would face the MIPS payment adjustments for the applicable year. We are requesting approval of 2 information collections associated with the MAQI Demonstration: (a) A Qualifying Payment Arrangement Submission Form and (b) a Threshold Data Submission Form. Subsequent to publishing the 60-day **Federal Register** notice (83 FR 31150), there have been minor revisions made to the collection instrument to clarify information. There is no increase in the burden hours. *Form Number:* CMS–10673 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 1,500,000. (For policy questions regarding this collection contact John Amoh at *john.amoh@cms.hhs.gov.*)

Dated: September 14, 2018.

Martique Jones,

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

[FR Doc. 2018–20372 Filed 9–18–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3152]

Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability'' that appeared in the **Federal Register** of September 11, 2018. The document announced a draft guidance that provides recommendations to holders of approved new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files and veterinary master files who may want to make a change to the drug substance manufacturing process during the drug product application postapproval period. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, September 11, 2018 (83 FR 45944), in FR Doc. 2018–19666, on page 45944, the following correction is made:

On page 45944, in the first column, in the header of the document, and also in the third column under *Instructions,* ''Docket No. FDA–2018–D–3151'' is corrected to read ''Docket No. FDA–2018–D–3152''.

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20317 Filed 9–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0029]

Agency Information Collection Activities: Application for Foreign-Trade Zone Admission and/or Status Designation, and Application for Foreign-Trade Zone Activity Permit

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted no later than October 19, 2018 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 83 FR Page 23286) on May 18, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Application for Foreign-Trade Zone Admission and/or Status Designation, and Application for Foreign-Trade Zone Activity Permit.

OMB Number: 1651–0029.

Form Numbers: 214, 214A, 214B, 214C, and 216.

Type of Review: Extension (without change).

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Forms 214, 214A, 214B, 214C, and 216.

Affected Public: Businesses.

Abstract: Foreign trade zones (FTZs) are geographical enclaves located within the geographical limits of the United States but for tariff purposes are considered to be outside the United States. Imported merchandise may be brought into FTZs for storage, manipulation, manufacture or other processing and subsequent removal for exportation, consumption in the United States, or destruction. A company bringing goods into an FTZ has a choice of zone status (privileged/non-privileged foreign, domestic, or zone-