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 February 26, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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:* Revision of a currently approved Information Collection; *Title of Information Collection:* CMS Plan Benefit Package (PBP) and Formulary CY 2025; *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. CMS uses this data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans. *Form Number:* CMS–R–262 (OMB control number: 0938–0763); Frequency: Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 825; *Total Annual Responses:* 8,770; *Total Annual Hours:* 55,782 (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209.)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Satisfaction of Nursing Homes, Hospitals, and Outpatient Clinicians Working with the CMS Network of Quality Improvement and Innovation Contractors Program (NQIIC); *Use:* The purpose of this Information Collection Request (ICR) is to collect data to inform the program evaluation of the Centers for Medicare & Medicaid Services (CMS) Quality Innovation Network-Quality Improvement Organization (QIN–QIO) and Hospital Quality Improvement Contractors (HQIC) programs under the Network of Quality Improvement and Innovation Contractors (NQIIC) contract vehicle. This is a revision package. First, we updated the Nursing Home and Hospital Surveys to cover all the quality improvement focus areas targeted by NQIIC awardees, removed some but not all COVID–19 Public Health Emergency (PHE) related questions to reflect the progress of Federal health program (*e.g.,* Agency for Healthcare Research and Quality Project Echo program was officially ended in August 2021), and made minor refinements based on the first round of survey fielding. Second, we added the Outpatient Clinician Survey in the same revision package since all three surveys are conducted under the same NQIIC contract.

This revision package supports evaluation of the technical assistance provided by the QINQIO Program to nursing homes and outpatient clinicians in community settings, and Hospital Quality Improvement Contractors (HQIC) Program activities to support hospitals. This ICR is part of a larger evaluation of the overall impact of the NQIIC Program. *Form Number:* CMS–10769 (OMB control number: 0938–1424); *Frequency:* Yearly; *Affected Public:* State and Private Sector (Business or other for-profits); *Number of Respondents:* 1,900; *Total Annual Responses:* 1,900; *Total Annual Hours:* 559. (For policy questions regarding this collection, contact Jeff Mokry at 214–767–4021.)

Dated: January 19, 2024.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–01383 Filed 1–24–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5706]

Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for a limited number of establishments to participate in a voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program involving the use of a prototype assessment protocol to evaluate quality management maturity (QMM). The Center for Drug Evaluation and Research (CDER) is implementing this voluntary program for manufacturers of CDER-regulated drug products to gain experience with the prototype assessment protocol and to evaluate whether use of the protocol, as designed, will enable a meaningful assessment of the establishment's

quality management practices while providing useful feedback for the establishment. This notice outlines the types of establishments FDA is seeking for participation and the process for submitting a request to participate in the program.

DATES: FDA intends to accept requests to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program through March 25, 2024. See the ''Participation'' section of this document for instructions on submitting a request to participate and the selection process.

FOR FURTHER INFORMATION CONTACT: *For questions about the voluntary QMM Prototype Assessment Protocol Evaluation Program:* Djamila Harouaka, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4160, Silver Spring, MD 20993–0002, 240–402–0224, *CDER-QMM@fda.hhs.gov.*

To submit a request to participate in the program: Conchetta Newton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4144, 240–402–6551, *CDER-QMM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

QMM refers to the extent to which drug manufacturing establishments implement quality management practices that prioritize patients, drive continual improvement, and enhance supply chain reliability through the strategic integration of business decisions and manufacturing operations with quality practices and technological advancements. CDER is in the process of developing a voluntary program to promote QMM at drug manufacturing establishments, which would encourage drug manufacturers to implement quality management practices that go beyond current good manufacturing practice (CGMP) requirements.[1]

As part of the QMM program initiative, CDER is developing a QMM Assessment Tool (including both a protocol and rubric) to evaluate how effectively establishments monitor and manage quality and quality systems.[2] In FY 2024, CDER intends to launch the voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program to gain experience with use of a prototype of the assessment protocol to evaluate whether use of the protocol, as currently designed, will enable a meaningful assessment of the establishment's quality management practices and actionable feedback for the establishment. The outcomes from this prototype evaluation program will help to inform the development of the QMM Assessment Tool to be used in the eventual QMM program. This notice announces FDA's intent to launch the QMM Prototype Assessment Protocol Evaluation Program, outlines the types of establishments FDA is seeking for participation, and describes the process for submitting a request to participate in the program.

Between October 2020 and March 2022, CDER conducted under contract two pilot programs to assess the QMM of drug manufacturing establishments. The first pilot program evaluated the maturity of seven domestic manufacturers of finished dosage forms for the U.S. market (Ref. 1). The second pilot program evaluated the maturity of eight foreign manufacturers of active pharmaceutical ingredients (APIs) (Ref. 2). Each pilot program was conducted by a different contractor. These pilot programs provided valuable insights to CDER for developing a protocol to assess establishments' QMM, understanding assessor behaviors during interviews of establishment personnel, and gathering participant feedback on assessment questions, reports, and outcomes (Ref. 3).

Using findings from these two pilot programs, a review of the quality management maturity literature, evaluations of existing external programs assessing elements of quality culture or pharmaceutical quality, surveys of external stakeholders, and feedback from partner offices and centers within FDA, CDER has developed a prototype assessment protocol to evaluate an establishment's QMM. The prototype assessment protocol includes a series of questions in five practice areas: leadership, business continuity, technical excellence, advanced pharmaceutical quality system, and employee empowerment and engagement. Within each practice area, the prototype assessment protocol explores key elements of the establishment's QMM. Examples of some topics that may be covered under the practice areas include: management review and resource management (management commitment to quality), supply planning and demand forecasting (business continuity), corrective action and preventive action process (advanced pharmaceutical quality system), data governance and process optimization (technical excellence), and rewards and recognition (employee engagement and empowerment). CDER will use the standardized prototype assessment protocol to collect information on an establishment's executed practices, behaviors, and responses to specific questions, and will evaluate this information using an objective rubric to help identify areas of strength and potential areas with opportunities for improvement.

Prototype assessment protocols will be conducted by trained assessors who will engage directly with establishments, either onsite or in a hybrid (both virtual and onsite) environment. Assessments are anticipated to take up to five business days and are distinct from FDA's regulatory inspections.

II. Participation

A. Establishment Characteristics

CDER will consider the following establishment characteristics when identifying potential participants for this QMM Prototype Assessment Protocol Evaluation Program:

- The potential participant is an establishment as defined in 21 CFR 207.1 that registers with FDA under section 510 (21 U.S.C. 360) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and manufactures, prepares, propagates, compounds, or processes drugs, or APIs used in such drugs, subject to approval or licensure under section 505 (21 U.S.C. 355) of the FD&C Act or section 351 of the Public Health Service Act (42 U.S.C. 262), or that are marketed pursuant to section 505G of the FD&C Act without an approved application under section 505 of the FD&C Act (often referred to as over-the-counter (OTC) monograph drug products).
- The establishment received at least one human drug surveillance inspection [3] in the prior 5 years.
- The current inspection classification for the establishment at the time of the request to participate is No Action Indicated or Voluntary Action Indicated.
- The establishment manufactures, prepares, propagates, compounds, or processes at least one CDER-regulated drug (API or finished drug product) that

[1] FDA has solicited comments to inform the development of this program. See 88 FR 63587, September 15, 2023.

[2] For additional information, see *CDER's Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development* (2023), available at *https://www.fda.gov/media/171705/download?attachment.*

[3] Inspections conducted by FDA or by Mutual Recognition Agreement (MRA) partners and classified by FDA would fulfill this criterion. See Mutual Recognition Agreements (MRA) for more information.

is currently in commercial distribution in the United States.

- The establishment is willing to participate in an onsite or hybrid assessment.

B. Requests To Participate

Drug product manufacturers that are eligible and interested in participating in the voluntary QMM Prototype Assessment Protocol Evaluation Program should submit a request directly to Conchetta Newton (see **FOR FURTHER INFORMATION CONTACT**). To be considered for this program, a request should include all the following information: (1) a contact person (name and email); (2) manufacturing establishment address; (3) FDA Establishment Identifier and Data Universal Numbering System Numbers; (4) a brief description of the business operations (*e.g.,* manufacturing, testing, re/packaging, re/labeling, sterilizing, storing, distributing, or salvaging) conducted at the establishment; and (5) confirmation that the establishment features the characteristics discussed in section II.A of this notice.

C. Selection Process

FDA intends to select participants that reasonably reflect the diversity of the industry. FDA intends to notify each establishment of FDA's decision on their request to participate in the voluntary QMM Prototype Assessment Protocol Evaluation Program within 90 days of receipt. FDA intends to select up to nine volunteer participants for this program.

D. FDA-Participant Interactions

FDA intends to notify selected participants of their selection and confirm participation. This notification will include more information about engagement with the Agency, including an orientation and a pre-assessment questionnaire to assist the establishment in preparing for the assessment, logistical information such as options for dates and times to schedule the assessment, and recommendations for establishment personnel that should be available during the assessment. Teams of three assessors will conduct the prototype assessment protocol over a period that is expected to be up to five business days. Each team will be composed of CDER staff, or a combination of CDER staff and contractors. Following completion of the assessment, each participating establishment will receive a report summarizing areas of strength and growth opportunities. In addition, approximately 6 months after the assessment, FDA will followup with a virtual meeting to get feedback on the prototype assessment protocol, the report, and any limitations encountered. This will help the Agency evaluate use of the protocol, including whether it enables meaningful assessment of the establishment's quality management practices and if feedback for the establishment is actionable.

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement,'' 85 FR 65824, October 16, 2020, *https://www.federalregister.gov/d/2020-22976.*

* 2. ''Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement,'' 85 FR 65828, October 16, 2020, *https://www.federalregister.gov/d/2020-22977.*

3. J. Maguire, A. Fisher, D. Harouaka, N. Rakala, et al., 2023, ''Lessons from CDER's Quality Management Maturity Pilot Programs,'' *AAPS Journal,* 25(14), January 10, 2023, *https://doi.org/10.1208/s12248-022-00777-z.*

Dated: January 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01423 Filed 1–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to Coronavirus Disease 2019 (COVID–19). FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: