comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993–0002, 301–796–7997, *jonathan.resnick@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is issuing this **Federal Register** notice pursuant to the guidelines described in the FDA guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act'' (December 2014, available at *https://www.fda.gov/media/88120/download*), section III.F ''When will revisions or updates to existing formats take effect?'' to announce the end of support for electronic submissions using eCTD Module 1 U.S. Regional DTD Version 2.01 and the date the requirement begins to submit using eCTD Module 1 U.S. Regional DTD Version 3.3 as described in this notice.

On June 15, 2015, FDA began accepting electronic submissions using eCTD Module 1 U.S. Regional DTD Version 3.3 as described in ''The eCTD Backbone Files Specification for Module 1'' Version 2.3. This upgrade of eCTD Module 1 includes functionality for promotional material and risk evaluation and mitigation strategies submissions, the ability to dynamically update certain heading elements (*e.g.,* FDA forms), and the ability to submit grouped submissions. FDA has continued to accept electronic submissions using the previous version of the eCTD Module 1, using U.S. Regional DTD Version 2.01 as described in ''The eCTD Backbone Files Specification for Module 1'' Version 1.3.

Due to the limitations of eCTD Module 1 U.S. Regional DTD Version 2.01, FDA support for electronic submissions using eCTD Backbone Files Specification for Module 1 Version 1.3, Comprehensive Table of Contents Headings and Hierarchy Version 1.2.2, U.S. Regional DTD Version 2.01, and U.S. Regional Stylesheet Version 1.1 will end on March 1, 2022. The requirement for electronic submissions to be submitted using eCTD Module 1 U.S. Regional DTD Version 3.3 will begin on March 1, 2022. The Agency will update the eCTD Submission Standards document to reflect these changes.

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22971 Filed 10–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2018]

Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency), Center for Drug Evaluation and Research (CDER) is announcing its Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program (QMM API Pilot Program) for foreign facilities manufacturing active pharmaceutical ingredients (APIs), including facilities manufacturing drug substance intermediates used to produce APIs, that are used in FDA-regulated prescription and over-the-counter (OTC) drug products. The purpose of the QMM API Pilot Program is to gain insight from third-party assessments of a facility's quality management system to inform future development of an FDA rating system to characterize quality management maturity (QMM). Such a rating system would allow a cross-sectional comparison of facilities. Facilities that choose to disclose their facility ratings to drug product manufacturers could benefit from a competitive advantage, as knowledge of QMM ratings would enable drug product manufacturers to differentiate among facilities when purchasing APIs. This notice invites foreign facilities that are interested in participating in the QMM API Pilot Program to submit a request to participate.

DATES: FDA will accept requests to participate in the QMM API Pilot Program through November 30, 2020, and the QMM API Pilot Program will run through December 31, 2021. See the ''Participation'' section for selection criteria and instructions on how to submit a request to participate.

FOR FURTHER INFORMATION CONTACT: *For general questions about the QMM API Pilot Program:* Jennifer Maguire, Center for Drug Evaluation and Research (CDER), 10903 New Hampshire Ave., Bldg. 51, Rm. 4134, Silver Spring, MD 20993, 240–402–4817, *Jennifer.Maguire@fda.hhs.gov.*

To submit a request to participate in the QMM API Pilot Program: Seongjin (Cindy) Pak, CDER, 10903 New Hampshire Ave., Bldg. 51, Rm. 4220, 301–796–1673, *Seongjin.Pak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 2002, FDA launched an initiative ''Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach,'' to enhance and modernize the regulation of pharmaceutical manufacturing and product quality.[1] One objective, among others, was to facilitate the implementation of a modern, risk-based

[1] See FDA's final report: ''Pharmaceuticals CGMPs for the 21st Century—A Risk-Based Approach'' (September 2004) at *https://www.fda.gov/media/77391/download.*

pharmaceutical quality assessment system. The desired goal has been described as a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.

There has been significant progress toward this vision as evidenced by FDA programs and initiatives in such areas as pharmaceutical development and quality by design, quality risk management and pharmaceutical quality systems, process validation, and emerging technologies. These programs and initiatives promote use of the best pharmaceutical science and engineering principles throughout the product life cycle.

Another example is the FDA Quality Metrics Program, described in the November 2016 revised draft guidance for industry, ''Submission of Quality Metrics Data'' (81 FR 85226). When final, this guidance will represent FDA's current thinking on this issue. In June 2018, FDA initiated two voluntary programs that sought additional industry input on quality metrics. FDA solicited industry participation for a Site Visit Program (83 FR 30751) for manufacturing establishments to present the advantages and challenges associated with implementing and managing a quality metrics program and for a Quality Metrics Feedback Program (83 FR 30748) to engage stakeholders in identifying mutually useful and objective quality metrics.

The Agency continues to develop the FDA Quality Metrics Program but recognizes that quality metrics are only one element within a manufacturer's larger effort to increase the maturity of their quality management system. Manufacturers that demonstrate QMM [2] operate under an enhanced quality management system that exceeds the minimum standards specified in current good manufacturing practice regulations and focuses on continual improvement. Characteristics of a mature quality management system include, for example, the ability to consistently and reliably deliver quality product over time, operational stability, and a strong quality culture. Additionally, for manufacturers with a mature quality management system, FDA can exercise a more flexible regulatory approach, leading toward the goal of producing high-quality drug products without extensive regulatory oversight.

[2] For additional information on quality management maturity, see FDA's Report: ''Drug Shortages: Root Causes and Potential Solutions'' (October 2019) at *https://www.fda.gov/media/131130/download.*

A transparent method of evaluating and communicating QMM is needed to fully realize the 21st century pharmaceutical quality vision. Toward that end, FDA is announcing the start of the QMM API Pilot Program. Through this pilot program, a third-party contractor identified by the FDA will conduct an assessment of a facility's quality management system, accompanied by FDA staff. The Agency will gain insight from the results of the QMM assessments to inform the development of a rating system to measure and rate QMM. Assessments under the QMM API Pilot Program will cover multiple topics. Examples include but are not limited to:

1. Supply chain management;
2. manufacturing strategy and operations;
3. safety, environmental, and regulatory compliance;
4. inventory management;
5. performance management and continual improvement;
6. risk management;
7. management review and responsibility;
8. planning;
9. workforce management;
10. quality culture; and
11. customer experience.

In the same timeframe as the QMM API Pilot Program, FDA will conduct a QMM pilot program for domestic manufacturers of finished dosage forms (FDF). These pilot programs are funded separately and are intended to provide FDA with representative information about QMM from different types of drug manufacturers (API and FDF). Elsewhere in this issue of the **Federal Register,** FDA is publishing ''Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement.''

II. Participation

Facilities located outside the United States that manufacture APIs or drug substance intermediates used to produce APIs and are interested in participating in the QMM API Pilot Program should submit a written request directly to Seongjin (Cindy) Pak (see **FOR FURTHER INFORMATION CONTACT**). Participation is voluntary. Participants in the Quality Metrics Feedback Program are encouraged to participate in the QMM API Pilot Program. FDA will select up to nine participants for the QMM API Pilot Program. Participation in the QMM API Pilot Program is limited to foreign manufacturing facilities since FDA's funding source for this program is specific to activities related to the surveillance of foreign sites.

A. Selection Criteria

To be considered for the QMM API Pilot Program, participants must meet the following selection criteria:

1. Participant is a facility located outside the United States that manufactures APIs or drug substance intermediates used to produce APIs for FDA-regulated prescription and OTC drug products. Facilities located in Puerto Rico or other U.S. territories are not considered to be foreign facilities and thus are not eligible to participate in the QMM API Pilot Program.

2. All FDA inspection(s) of the manufacturing facility conducted within the 5 years prior to September 15, 2020, received a final classification of ''No Action Indicated'' or ''Voluntary Action Indicated.''

3. Participant agrees to:

a. Permit a third-party contractor to conduct a QMM assessment, whether the assessment is conducted on-site or remotely. FDA will identify an external contractor having the expertise to assess QMM, and FDA staff will join the contractor for the assessment.

b. Collect and submit metric data to FDA and the contractor by an agreed upon date, prior to the assessment. As part of the scoping discussions for the assessment, FDA will provide the facility with templates and additional details about the data collection.

c. Be available for consultations with the contractor and FDA prior to and after the assessment, including discussions regarding the participant's established QMM-related activities and the contractor's post-assessment recommendations regarding these activities.

During this QMM API Pilot Program, the contractor and FDA staff will be available to answer questions and address concerns that arise.

B. Information To Include in the Request

When submitting a request to participate in the QMM API Pilot Program, include the information below to aid in FDA's selection and planning. FDA will not consider requests submitted without the following minimal information:

1. A contact person (name and email);
2 facility location;
3. facility FDA Establishment Identifier and Data Universal Numbering System numbers;
4. a brief description of the manufacturing operations conducted at the facility;
5. preferred dates for the assessment;

6. written confirmation that the facility meets the selection criteria in section II.A, including agreement to items 3a–c;

7. written confirmation that the facility can handle a visit of up to 10 FDA staff and contractors; and

8. a brief description of prior experiences undergoing an assessment related to the maturity of the facility's quality culture, including the name of the organization that conducted the assessment and date of the assessment.

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22977 Filed 10–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which a manufacturer or distributor of a new dietary ingredient or of a dietary supplement containing a new dietary ingredient is to submit to FDA information upon which it has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

DATES: Submit either electronic or written comments on the collection of information by December 15, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 15, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 15, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0878 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–420–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests