

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total .....	.....	.....	.....	.....	1,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the recordkeeping burden under § 179.25(e) is based on our experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. We estimate that there are four irradiation plants whose business is devoted primarily (*i.e.*, approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. We estimate that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on four facilities devoting 100 percent of their business to food irradiation, and four facilities devoting 10 percent of their business to food irradiation.

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the disclosures are supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by OMB under the PRA.

Dated: October 9, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-1216]

**Electronic Common Technical Document; Data Standards; Support Ends for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 2.01 and Requirement Begins for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 3.3**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration’s (FDA or Agency) Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are announcing the date that FDA will no longer support electronic submissions using the Electronic Common Technical Document (eCTD) Backbone Files Specification for Module 1 Version 1.3, Comprehensive Table of Contents Headings and Hierarchy Version 1.2.2, U.S. Regional Document Type Definition (DTD) Version 2.01, and U.S. Regional Stylesheet Version 1.1, and will require electronic submissions to be submitted using eCTD Module 1 U.S. Regional DTD Version 3.3. The Agency will update the eCTD Submission Standards document to reflect these changes.

**DATES:** 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.

**ADDRESSES:** You may submit either electronic or written comments at any time as follows:

*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-2018-D-1216 for “Electronic Common Technical Document; Data Standards; Support Ends for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 2.01 and Requirement Begins for Electronic Common Technical Document Module 1 U.S. Regional Document Type Definition Version 3.3.” Received comments 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, 240-402-7500.

- *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:** 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](mailto: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.*

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## 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](mailto: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](mailto: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.<sup>1</sup> One objective, among others, was to facilitate the implementation of a modern, risk-based

<sup>1</sup> 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>.