Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes'' (July 2019), there are various processes by which appeals requests regarding review of decisions or actions by CDRH may be submitted to the Agency. The guidance is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.* The guidance document provides general format and content recommendations in this regard, discusses applicable regulations with regard to the timing of such submissions, and describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information. While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled ''Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff'' (March 2020), also available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.*

In the **Federal Register** of February 18, 2022 (87 FR 9365) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

CDRH Appeals Processes: Guidance for Industry and FDA Staff	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Recommended format and content elements	35	1	35	8	280

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate 35 requests will be submitted annually to review decisions and actions by CDRH employees, we attribute one respondent per submission, and we assume each request will take 8 hours to prepare. Based on our evaluation of the information collection since last OMB approval, we have made no adjustments to the currently approved burden estimate.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18065 Filed 8–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2544]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice; Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 recordkeeping requirements related to the medical devices current good manufacturing practice (CGMP) quality system (QS) regulation (CGMP/QS regulation).

DATES: Either electronic or written comments on the collection of information must be submitted by October 21, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2016–N–2544 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice; Quality System Regulation.'' 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, 240–402–7500.

• 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Current Good Manufacturing Practice Quality System Regulation—21 CFR Part 820

OMB Control Number 0910–0073—Extension

As authorized under section 520(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services has issued regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device, but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, and assure that the device will be safe and effective and otherwise in compliance with the FD&C Act.

The QSR under part 820 (21 CFR part 820) sets forth CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. The requirements cover purchasing and service controls, clarify recordkeeping for device failure and complaint investigations, clarify requirements for verifying/validating production processes and process or product changes, and clarify requirements for product acceptance activities, quality data evaluations, and corrections of nonconforming product/quality problems. In the **Federal Register** of February 23, 2022 (87 FR 10119), we proposed to incorporate by reference International Organization for Standardization 13485 (ISO 13485): Medical devices—Quality Management Systems—Requirements for Regulatory Purposes, the 2016 edition, to the QSR (RIN 0910–AH99), to align implementation of requirements.

Information collection under the QSR is intended to assist FDA in assuring the safety of medical devices. Requirements include documenting the establishment of procedures and identifying required records that assist FDA in determining whether firms are in compliance with CGMP. In particular, for example, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted in deaths and serious injuries. Records must be made available for review or copying during FDA inspection. The regulations in part 820 apply to approximately 29,424 respondents, based on current data within our device registration and listing database.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 820; required records	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
QUALITY SYSTEM REQUIREMENTS—Subpart B	29,424	1	29,424	83	2,442,192
DESIGN CONTROLS—Subpart C	29,424	1	29,424	132	3,883,968
DOCUMENT CONTROLS—Subpart D	29,424	1	29,424	11	323,664
PURCHASING CONTROLS—Subpart E	29,424	1	29,424	28	823,872
IDENTIFICATION & TRACEABILITY—Subpart F	29,424	1	29,424	2	58,848
PRODUCTION & PROCESS CONTROLS—Subpart G	29,424	1	29,424	31	912,144
ACCEPTANCE ACTIVITIES—Subpart H	29,424	1	29,424	6	176,544
NONCONFORMING PRODUCT; CORRECTIVE & PREVENTATIVE ACTION—Subparts I and J	29,424	1	29,424	23	676,752
LABELING & PACKAGING CONTROLS—Subpart K	29,424	1	29,424	3	88,272
HANDLING, STORAGE, DISTRUBTION, & INSTALLATION—Subpart L	29,424	1	29,424	15	441,360
RECORDS—Subpart M	29,424	1	29,424	10	294,240
SERVICING—Subpart N	29,424	1	29,424	3	88,272
STATISTICAL TECHNIQUES—820.250—Subpart O	29,424	1	29,424	1	29,424
Totals					10,239,552

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 1,217,800 hours. We made this adjustment to correspond with an observed increase in submissions relating to medical devices and an increase in respondents in the medical device industry since last OMB review and approval of the information collection.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18072 Filed 8–19–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–N–1222; FDA–2015–N–3662; FDA–2013–N–1425; FDA–2008–D–0530; FDA–2019–N–0482; FDA–2021–N–1192; FDA–2018–N–4042; FDA–2015–N–3815; FDA–2019–N–0721; and FDA–2013–N–0013]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Food Labeling: Notification Procedures for Statements on Dietary Supplements	0910–0331	7/31/2025
Guidance for Reagents for Detection of Specific Novel Influenza A Viruses	0910–0584	7/31/2025
Mitigation Strategies to Protect Food Against Intentional Adulteration	0910–0812	7/31/2025
Tropical Disease Priority Review Vouchers	0910–0822	7/31/2025
Reporting Associated with New Animal Drug Applications and Veterinary Master Files	0910–0032	8/31/2025
Substances Generally Recognized as Safe: Notification Procedure	0910–0342	8/31/2025
Establishing and Maintaining Lists of U.S. Product Manufacturers/Processors With Interest in Exporting CFSAN-Regulated Products	0910–0509	8/31/2025
Electronic Submission of Medical Device Registration and Listing	0910–0625	8/31/2025
Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications	0910–0750	8/31/2025
Sanitary Transportation of Human and Animal Food	0910–0773	8/31/2025