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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2544]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 current good manufacturing practice (CGMP) and assure that the device will be safe and effective and otherwise in compliance with the FD&C Act.

The quality system regulation (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.

In the *Federal Register* of August 22, 2022 (87 FR 51433), we published a 60-day notice soliciting 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 Recordkeeping Burden[1]

21 CFR Part 820; Required Records	No. of Recordkeepers	No. 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 and Traceability--Subpart F	29,424	1	29,424	2	58,848
Production and 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 and Preventative Action--Subparts I And J	29,424	1	29,424	23	676,752
Labeling and Packaging Controls--Subpart K	29,424	1	29,424	3	88,272
Handling, Storage, Distribution, and 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--section 820.250--Subpart O	29,424	1	29,424	1	29,424
Total					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: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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