time required for this collection of information is 25 hours. Based on a review of the information collection and the number of notifications received since 2018, we have made no adjustments to our burden estimate.

Dated: December 8, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27011 Filed 12–12–22; 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; 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 January 12, 2023.

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	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 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.

[FR Doc. 2022–27023 Filed 12–12–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1794]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Drug Labeling Provisions and Over-the-Counter Monograph Drug User Fee Submissions

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 January 12, 2023.

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 0910–0340. 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.

General Drug Labeling Provisions and OTC Monograph Drug User Fee Submissions—21 CFR Part 201

OMB Control Number 0910–0340—Revision

I. Over-the-Counter (OTC) Drug Product Labeling

This information collection supports implementation of general drug labeling provisions, including certain OTC drug product labeling requirements found in FDA regulations in 21 CFR part 201 and in section 502(x) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(x)), as well as OTC drug product labeling recommendations discussed in FDA guidance documents enumerated below. The requirements and recommendations contained in this authority help ensure that OTC drug product labeling includes information to assist consumers with product selection and with the safe and effective use of products that protect the public health from potential harm that could result from the dissemination of false and misleading statements regarding FDA-regulated products. As described further below, the information collection provisions of one guidance also apply to prescription drug labeling.

A. Principal Display Panel Labeling

Certain information collection provisions address the labeling (third-party disclosures) that drug companies provide on the principal display panel of every OTC drug product in package form—the part of that drug product's label that is most likely to be displayed or examined in a retail sale setting (see 21 CFR 201.60). Information on this panel supports consumers' product selection, as well as identification after purchase. OTC drug product companies must include a declaration of the net quantity of the OTC product contents on the principal display panel (see § 201.62 (21 CFR 201.62)). They also must include a statement of identity (see § 201.61 (21 CFR 201.61)).

FDA has made available a draft guidance for industry entitled ''Statement of Identity and Strength—Content and Format of Labeling for Human Nonprescription Drug Products'' [1] (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quantitative-labeling-sodium-potassium-and-phosphorus-human-over-counter-and-prescription-drug*) that further addresses content and format of statement of identity information and drug product strength information to be included in the principal display panel labeling of human nonprescription drug products. The guidance provides recommendations to help manufacturers comply with statement of identity labeling requirements under § 201.61 and also provides a recommended alternative to the statement required by that regulation to provide consumers with consistent information about the active ingredients, strength, and dosage form of the product. Consistent information about the active ingredients, strength, and dosage form of the product on the principal display panel may aid consumers in comparing nonprescription drug products and assist consumers in appropriate self-selection of these products and in subsequent identification of the products after purchase.

In estimating burden for statement of identity labeling, we have excluded the burden for disclosing any statement of identity specified in a final OTC monograph order under section 505G of the FD&C Act (21 U.S.C. 355h), because FDA regulations state that for purposes of § 201.61, the statement of identity shall be the term or phrase used in an applicable OTC monograph (see 21 CFR 330.1(c)(1)). By operation of law, OTC monographs are now established by order under section 505G of the FD&C Act, and information collections made under section 505G are exempt from the PRA under section 505G(o) of the FD&C Act.

B. OTC Drug and Prescription Drug Facts Labeling

In addition to labeling that drug companies provide on the principal display panel, companies must also comply with Agency regulations in § 201.66 (21 CFR 201.66), which requires standard content elements and formatting for the ''Drug Facts'' labeling (DFL) of all OTC drug products. This standardized labeling helps consumers understand the information that appears on OTC drug products to help ensure that consumers can use those products safely and effectively. The use of consistent language in labeling headings and subheadings helps consumers comprehend information, and consistent formatting helps consumers more efficiently locate information.

The DFL is where OTC drug product labeling presents certain specific, standardized content required or recommended under other regulations

[1] When final, this guidance will represent FDA's current thinking on this topic.