June 18, 2024, (89 FR 51738) (RIN 0910–AC53), current good manufacturing practice requirements applicable to medical gas are now established in 21 CFR parts 213 and 230 and accounted for under OMB control number 0910–0906.

In the **Federal Register** of February 20, 2026 (91 FR 8249), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, the comments were not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—APIS AND FINISHED PHARMACEUTICALS [1] [2]

Information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CGMP API Manufacturers	1,260	256	322,560	0.82 (49.2 minutes)	264,499
CGMP Finished Pharmaceuticals Manufacturers (excludes medical gases).	3,270	299	977,730	0.64 (38 minutes)	625,747
Voluntary Consensus Standard Activities	9	1	9	1	9
AMT Program Activities, including designation requests	20	1	20	10	200
Total			1,300,319		890,455

[1] There are no capital or operating and maintenance costs associated with the information collection.
[2] Records and burden per activity have been averaged and rounded.

Our estimated burden for the information collection reflects a decrease of 396,293 hours and 639,491 responses annually, resulting from removal of burden attributable to information collection for medical gas requirements. We have otherwise retained currently approved estimates, noting that the AMT activity element has been inadvertently omitted from our burden summary table that appears at *www.reginfo.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10188 Filed 5–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0497]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

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 June 22, 2026.

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 0910–0233. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *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.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions—21 CFR Part 60

OMB Control Number 0910–0233—Extension

This information collection supports Agency regulations. FDA's patent extension activities are conducted under the authority of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (Pub. L. 100–670) (21 U.S.C. 301, *et seq.*). The regulations are codified in part 60 (21 CFR part 60), Patent Term Restoration. New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. If the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent.

In enacting section 505(j) of the FD&C Act and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years and is calculated by USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

In 21 CFR 60.36(a) *due diligence* is defined as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily

exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates, if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

In the **Federal Register** of February 18, 2026 (91 FR 7497), FDA published a 60-day notice requesting public comment on the proposed collection of information with respect to the following 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. One multi-part comment was received.

The commenter affirms that this information collection is necessary for the FDA to administer the Patent Term Extension provisions of the Hatch-Waxman Act. The commenter asserts, however, that the information collection's value is contingent on whether it produces clear, reliable, and appropriately bounded information, and that the low volume of petitions received may suggest that the process is underutilized. The commenter notes that due diligence petitions and requests to revise regulatory review period determinations are not purely administrative exercises—they frequently require integration of legal analysis, scientific and technical documentation, and detailed factual timelines, meaning actual burden may vary significantly and may exceed FDA's estimates in some cases. The commenter suggests that greater clarity regarding the types of information expected and the way it should be presented would improve both the efficiency and effectiveness of the collection. The commenter's suggestions generally imply that standardization and clear articulation of the due diligence process would reduce the burden on respondents. The commenter also made several comments about the background, purpose, and policy considerations of due diligence petitions concerning FDA regulatory review period determinations for patent term extensions pursuant to the Hatch-Waxman Act.

After thoroughly considering the commenter's thoughts on the information collections assessed burden, FDA will not currently adjust its burden estimates for the present submission until it analyzes additional burden information. The Agency will observe the program and process between now and the next renewal cycle. If evidence corroborates the commenter's observations, refinements to the information collection may be made at that time. Additionally, the commenter also made several comments about the background, purpose, and policy considerations of due diligence petitions and noted that the Agency should consider refining the definition of ''due diligence.'' We believe ''due diligence'' is adequately defined. We will not address the remaining comments here as they are outside the scope of this notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 60—patent term restoration	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Revision of regulatory review period determinations; § 60.24	4	1.25	5	100	500
Due diligence petitions; § 60.30	1	1	1	50	50
Due diligence hearings; § 60.40	1	1	1	10	10
Total					560

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

We base our estimates on our experience and the average number of requests for revision of regulatory review period determinations, due diligence petitions, and requests for hearing received in the past 3 years. We estimate that 4 respondents will submit an average of 1.25 requests for revision of the regulatory review period determinations annually, for a total of 5 requests received annually. We assume that it will take respondents 100 hours to prepare the factual and legal information necessary to submit a request for revision. Thus, we estimate a total reporting burden of 500 hours. We estimate that one or fewer due diligence petitions will be submitted annually and that will take a respondent 50 hours to prepare the petition, for a total of 50 hours. We estimate that one or fewer requests for hearing will be submitted annually and that it will take a respondent 10 hours to prepare the request for hearing, for a total of 10 hours.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10190 Filed 5–20–26; 8:45 am]

BILLING CODE 4164–01–P