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
Mammography Standards Quality Act Requirements	0910–0309	11/30/2025
510(k) Third-Party Review Program	0910–0375	11/30/2025
Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization	0910–0607	11/30/2025
Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	11/30/2025
Pilot to Develop Standardized Reporting Forms for Federally Funded Public Health Projects and Agreements	0910–0909	11/30/2025
Text Analysis of Proprietary Drug Name Interpretations	0910–0910	11/30/2025
Postmarket Surveillance of Medical Devices	0910–0449	12/31/2025
Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods	0910–0560	12/31/2025
Warning Plans for Smokeless Tobacco Products	0910–0671	12/31/2025
Deeming Tobacco Products To Be Subject to the FD&C Act	0910–0768	12/31/2025
Premarket Tobacco Product Applications and Recordkeeping Requirements	0910–0879	12/31/2025
Right to Try Act: Reporting Requirements	0910–0893	12/31/2025
Substances Generally Recognized as Safe: Best Practices for Convening a GRAS Panel	0910–0911	12/31/2025
Medical Devices—Quality System Regulation; 21 CFR part 820	0910–0073	1/31/2026
Threshold of Regulation for Substances Used in Food-Contact Articles	0910–0298	1/31/2026
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	0910–0312	1/31/2026
Mailing of Important Information About Drugs	0910–0754	1/31/2026
Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs	0910–0882	1/31/2026

Dated: February 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03073 Filed 2–13–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–3051 and FDA–2018–E–3095]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALIQOPA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ALIQOPA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 17, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 14, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 April 17, 2023. 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 Nos. FDA–2018–E–3051 and FDA–2018–E–3095 for Determination of Regulatory Review Period for Purposes of Patent Extension; ALIQOPA. 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.

• 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ALIQOPA (copanlisib dihydrochloride) indicated for treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies. Subsequent to this approval, the USPTO received patent term restoration applications for ALIQOPA (U.S. Patent Nos. 7,511,041 and RE46856) from Bayer Intellectual Property GmbH and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ALIQOPA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ALIQOPA is 3,004 days. Of this time, 2,821 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 26, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 26, 2009.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* March 16, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for ALIQOPA (NDA 209936) was initially submitted on March 16, 2017.

3. *The date the application was approved:* September 14, 2017. FDA has verified the applicant's claim that NDA 209936 was approved on September 14, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,594 or 692 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA

investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03070 Filed 2–13–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1048]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Requirements; Unique Device Identification

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 March 16, 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 0910–0485. 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 Device Labeling Requirements; Unique Device Identification

OMB Control Number 0910–0485—Revision

This information collection supports implementation of section 519(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i(f)), requiring the establishment of a unique device identification (UDI) system by FDA. Medical device labeling requirements governed by section 502 of the FD&C Act (21 U.S.C. 352) provide that every medical device and every device package bear a unique device identifier. Implementing regulations are found in part 801, subpart B (21 CFR part 801, subpart B) (Labeling Requirements for UDI), including provisions for exceptions from UDI requirements (21 CFR 801.30). Applicable regulations are also found in part 821 (21 CFR part 821) (Medical Device Tracking Requirements); 21 CFR part 822 (Postmarket Surveillance); part 814 (21 CFR part 814) (Premarket Approval of Medical Devices); and part 820 (21 CFR part 820) (Quality System Regulations), as well as regulations pertaining to in vitro device labeling, biological device product labeling, or any article subject to the device labeling provisions in section 502 of the FD&C Act. Products not in compliance with requirements set forth in the applicable statutory and regulatory authorities may be subject to enforcement action by FDA.

For operational efficiency, we are revising the information collection to include burden that may be attributable to activities associated with provisions found in part 830 (21 CFR part 830), currently approved in OMB control number 0910–0720 and established through rulemaking on September 24, 2013 (0910–AG31). The regulations define relevant terms, identify specific data requirements, and incorporate global standards applicable to the use and discontinuation of a UDI. The regulations also provide for FDA accreditation of an issuing agency (21 CFR 830.110) and explain associated information collection activities including the establishment, maintenance, and disclosure of records. Finally, the regulations provide for administration of the Global UDI Database (GUDID) (part 830, subpart E), which specifies data that must be submitted to FDA to be made publicly available. Users of the GUDID will be able to use the device identifier portion of the UDI to query descriptive data about a specific device. The GUDID may be accessed on our website at *https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid.*

In the **Federal Register** of August 24, 2022 (87 FR 51989), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received. However, upon further review and evaluation, we have made adjustments to our estimated burden for the collection of information, as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Part 801, subpart B: Labeling requirements for unique device identification	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Requirements for a unique device identifier under part 830	6,199	51	316,149	1	316,149

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

Our figures are based on economic analysis from previous Agency rulemaking. We assume most burden associated with activities applicable to satisfying UDI requirements as prescribed by part 830 is accounted for in currently approved information collections. For example, information collection associated with medical device tracking provisions in part 821 is currently approved in OMB control number 0910–0442; information collection associated with premarket approval of medical devices (part 814) is currently approved in OMB control number 0910–0231. Similarly, information collection associated with our quality system regulation (part 820)