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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device IMPELLA RP FLEX WITH SMART ASSIST. IMPELLA RP FLEX WITH SMART ASSIST is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. Subsequent to this approval, the USPTO received patent term restoration applications for IMPELLA RP FLEX WITH SMART ASSIST (U.S. Patent Nos. 9,402,942; 9,750,861; and 11,007,350) from Abiomed Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of IMPELLA RP FLEX WITH SMART ASSIST 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 IMPELLA RP FLEX WITH SMART ASSIST is 212 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, while 212 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* Not Applicable. The applicant claims that the length of the testing phase of the regulatory review period is 0 days.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* March 31, 2022. FDA has verified the applicant's claim that the premarket approval application (PMA) for IMPELLA RP FLEX WITH SMART ASSIST (PMA P170011/ Supplement (S039) was initially submitted March 31, 2022.

3. *The date the application was approved:* October 28, 2022. FDA has verified the applicant's claim that PMA P170011/S039 was approved on October 28, 2022.

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 212 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 § 60.30 (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 Nos. 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: June 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11026 Filed 6–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0734]

Agency Information Collection Activities; Proposed Collection; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the collection of information associated with our Manufactured Food Regulatory Program Standards (MFRPS).

DATES: Either electronic or written comments on the collection of information must be submitted by August 15, 2025.

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 August 15, 2025. 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–2025–N–0734 for ''Manufactured Food Regulatory Program Standards.'' 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: 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: 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.

Manufactured Food Regulatory Program Standards

OMB Control Number 0910–0601—Extension

This information collection helps implement FDA's ''Manufactured Food Regulatory Program Standards.'' Section 1012 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c) authorizes FDA to administer training and education programs for employees of State, local, Territorial, and Tribal food safety authorities relating to regulatory programs. Also, under section 205 of the FDA Safety Modernization Act (codified in 21 U.S.C. 2224), FDA, together with the Centers for Disease Control and Prevention, is directed to enhance foodborne illness surveillance to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. As part of this effort, we have initiated programs that include developing and instituting regulatory standards intended to reduce the risk of foodborne illness through coordinated efforts with our strategic partners. Regulatory program standards establish a uniform foundation for the design and management of State, local, Tribal, and Territorial programs that have the responsibility for regulating human and animal food. Partnering with other regulatory officials also helps maximize limited resources in administering FDA regulations pertaining to manufacturing/processing, packing, or holding of food for consumption in the United States.

The MFRPS are the result of external collaboration and coordination with the Association of Food and Drug Officials (AFDO) and State manufactured food regulatory programs. FDA, AFDO, and states worked collaboratively to develop the content of the MFRPS. A copy of the standards and accompanying worksheets and forms is available in the **Federal Register** docket for this notice. We recommend that State manufactured food regulatory programs use these program standards as the framework to design and manage their manufactured food regulatory programs. The States that assisted in the development of MFRPS were representative of the 42

State programs enrolled currently conducting manufactured food inspections via funding from a cooperative agreement grant entitled ''RFA–FD–18–001: Flexible Funding Model—Infrastructure Development and Maintenance for State Manufactured Food Regulatory Programs (U18).'' For more information on this cooperative agreement, visit our website at: *https://www.fda.gov/food/regulatory-program-standards-food/manufactured-food-regulatory-program-standards-mfrps.*

The regulatory program standards provide a uniform and consistent approach to manufactured food regulation in the United States. States may implement the program standards on a voluntary basis. The MFRPS is the framework that each participating State should use to design, manage, and improve its manufactured food regulatory program. The MFRPS provide for the following standards: (1) regulatory foundation; (2) training program; (3) inspection program; (4) inspection audit program; (5) food-related illness, outbreak and hazards response; (6) compliance and enforcement program; (7) industry and community relations; (8) program resources; (9) program assessment; and (10) laboratory support. For more information, including access to the program standards and appendices, visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards.*

The MFPS includes appendices to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the appendices provided with the standards. Other manual or automated forms, worksheets, and templates may be used if the pertinent data elements are present. Records and other documents specified in the standards must be current and fit for use by the State program and must be available to verify the implementation of each standard. As set forth in the standards, the State program is expected to develop or update a strategic improvement plan that aids the State program in achieving and maintaining conformance with the program elements of each standard and addresses any necessary corrective actions.

Description of Respondents: Respondents are State Departments of Agriculture or Health regulatory officials who enroll in the MFRPS. We estimate 42 respondents to the information collection based on current participation.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Type of respondent; information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Governments; Maintenance of data records consistent with the MFRPS	42	11	462	88.09	40,698

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

One State program is no longer participating in the MFRPS and two enrolled state agencies have been reorganized into one state agency since our last evaluation. We have consolidated our estimates from the previous request for renewal of this information collection to account for burden attributable to reporting tasks in the recordkeeping table. This consolidation of reporting and recordkeeping hours results in an increase in the average burden per recordkeeping. Due to the decrease in respondents, the total estimated burden for this collection has decreased by 1,938 hours.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10891 Filed 6–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–3588; FDA–2024–E–3589; and FDA–2024–E–3590]

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

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 XOLREMDI 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 **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by August 15, 2025. 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 December 15, 2025. 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 August 15, 2025. 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