the safety and effectiveness of the generic new animal drug.

The information collection also includes applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request. Therefore, the information collection references the guidance document GFI #171 ''Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-171-demonstrating-bioequivalence-soluble-powder-oral-dosage-form-products-and-type-medicated*) (June 2023), which discusses statutory bioequivalence requirements as well as qualifications for requesting a waiver from the requirements. The guidance document was developed consistent with the Agency's Good Guidance Practice regulations in 21 CFR 10.115, which provide for comment at any time.

The reporting associated with ANADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(2) of the FD&C Act. We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

Description of Respondents: The respondents for this collection of information are veterinary pharmaceutical manufacturers.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	9	1	9	159	1,431
Phased review with administrative ANADA	356v	21	5	105	31.8	3,339
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach	N/A	1	1	1	10	10
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for Type A medicated article, using same API/solubility approach	N/A	1	1	1	20	20
Total	.....	.....	.....	118	.....	4,810

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

We base our estimates on our records of generic animal drug applications. We estimate that we will receive 30 ANADA submissions per year over the next 3 years and that 21 of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated five ANADA phased review submissions and the administrative ANADA. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. Since our last review, we received only one biowaiver request for Type A medicated article using the same API, however we retain an estimate of one respondent for the remaining categories to permit such applications by respondents and also to permit related responses to FDA. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

Our estimated burden for the information collection reflects an overall increase of 511 hours and a corresponding increase of 55 responses. Based on a review of the information collection since our last request for OMB renewal, the increase in the burden hours estimate is attributable to an overall increase in the number of respondents submitting traditional and phased generic drug applications.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10887 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–2023–E–2612; FDA–2023–E–2613]

Determination of Regulatory Review Period for Purposes of Patent Extension; [AVEIR VR LEADLESS SYSTEM]

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 AVEIR VR Leadless System 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 medical device.

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 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–2023–E–2612; and FDA–2023–E–2613 for Determination of Regulatory Review Period for Purposes of Patent Extension; AVEIR VR LEADLESS SYSTEM. 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 § 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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 biological 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 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 AVEIR VR LEADLESS SYSTEM. AVEIR VR LEADLESS SYSTEM is indicated for patients with bradycardia and:

- Normal sinus rhythm with only rare episodes of A–V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

MR Conditional Aveir Leadless Pacemaker (LP) is conditionally safe for use in the MRI environment and according to the instructions in the Abbott MRI-Ready Leadless System Manual.

Aveir Delivery Catheter: The Aveir Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation include implanting an LP within the target chamber of the heart.

Aveir Link Module: The Aveir Link Module is intended to be used in conjunction with a Merlin PCS Programmer to interrogate and program an Aveir LP and to monitor LP function during an implant, retrieval, or follow-up procedure. Subsequent to this approval, the USPTO received patent term restoration applications for AVEIR VR LEADLESS SYSTEM (U.S. Patent Nos. 8,295,939; 9,168,383) from Pacesetter, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 18, 2024, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of AVEIR VR LEADLESS SYSTEM 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 AVEIR VR LEADLESS SYSTEM is 3,109 days. Of this time, 740 days occurred during the testing phase of the regulatory review period, while 2,369 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:* September 27, 2013. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the FD&C Act, became effective September 27, 2013.

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):* October 6, 2015. FDA has verified the applicant's claim that the premarket approval application (PMA) for AVEIR VR LEADLESS SYSTEM (PMA P150035) was initially submitted October 6, 2015.

3. *The date the application was approved:* March 31, 2022. FDA has verified the applicant's claim that PMA P150035 was approved on March 31, 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 1,826 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 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: June 11, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11028 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–2024–N–4731]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

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 July 16, 2025.

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 0910–0114. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Administrative Detention and Banned Medical Devices—21 CFR 800.55, 895.21, and 895.22

OMB Control Number 0910–0114—Extension

This information collection supports FDA regulations. FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), regarding administrative detention, includes among other things certain reporting requirements (§ 800.55(g)(1) and (2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices