biologic developers. FDA regulations in 21 CFR parts 210 and 211 govern current good manufacturing practice in the manufacturing, processing, packing, or holding of drugs and finished pharmaceuticals (including medical gases and active pharmaceutical ingredients), respectively. Applicable information collection and attendant burden are currently discussed, accounted for, and approved in OMB control number 0910–0139.

We are revising the information collection to include the AMT Designation Program within the scope of activity, as authorized by section 506L of the FD&C Act, and account for attendant burden. Requests for AMT designation are reviewed by FDA to evaluate whether the data and information submitted meets the criteria established in section 506L of the FD&C Act. If a request for AMT designation is granted, then future new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA) applicants may use or reference the designated AMT, noting specific application of the designated AMT to specific product development and inclusion in NDA, ANDA, or BLA submissions describing development and manufacturing processes. Also required by section 506L of the FD&C Act, we engaged with our stakeholders in a public meeting on June 8, 2023 (April 24, 2023, 88 FR 24807), to discuss innovative manufacturing technologies for drug and biological products and included a discussion of the AMT Designation Program. For more information regarding AMT, we invite readers to visit our website at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing,* which includes regular updates on Agency implementation of its AMT Designation Program.

Finally, section 506L of the FD&C Act also provides for the issuance of guidance. In the **Federal Register** of December 13, 2023 (88 FR 86333), we issued the draft guidance document entitled ''Advanced Manufacturing Technologies Designation Program,'' to communicate the goals, scope, and framework of the new program. We invited public comment under both our good guidance practices regulation in 21 CFR 10.115, and applicable PRA regulations in 5 CFR part 1320 and received a few comments. The comments included some requests for procedural clarification but focused mostly on requests for clarification of technical specifications and technologies that might qualify for AMT designation. Although we have updated the guidance document to address a number of public comments, we continue to implement the program and refine Agency processes.

FDA estimates the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 506L(c) FD&C Act	Number of respondents	Number of responses per respondents	Total annual responses	Average burden per response	Total hours
Submitting AMT designation requests; FDA Guidance for Industry, section III.B	20	1	20	10	200

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

Based on our experience with similar information collection activities that involve requests for FDA determinations, along with related preliminary and followup communications, we assume 10 hours is needed to complete the activities provided for in section 506L of the FD&C Act and discussed in the referenced guidance document. Although we have received fewer than 10 requests for AMT designation thus far, we are hopeful that 20 respondents will submit requests for AMT designation under the program.

Dated: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29954 Filed 12–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0195; FDA–2024–E–0196; FDA–2024–E–0197; FDA–2024–E–0198]

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

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 SOHONOS 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 February 18, 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 June 16, 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 February 18, 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–2024–E–0195, FDA–2024–E–0196, FDA–2024–E–0197, and FDA–2024–E–0198 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SOHONOS.'' 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, 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 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 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, SOHONOS (palovarotene) indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva. Subsequent to this approval, the USPTO received patent term restoration applications for SOHONOS (U.S. Patent Nos. 9,314,439 and 10,292,954 filed by Ipsen Biopharmsaceuticals, Inc. (agent of Thomas Jefferson University), and U.S. Patent Nos. 10,864,194 and 11,622,959, filed by Ipsen Biopharmaceuticals, Inc. (agent of Clementia Pharmaceuticals Inc.)), and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February l6, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SOHONOS 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 SOHONOS is 7,526 days. Of this time, 6,657 days occurred during the testing phase of the regulatory review period, while 869 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: January 9, 2003. The applicant claims April 27, 2014, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 9, 2003, which was 30 days after FDA receipt of an earlier IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: March 31, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for SOHONOS (NDA 215559) was initially submitted on March 31, 2021.

3. The date the application was approved: August 16, 2023. FDA has verified the applicant's claim that NDA 215559 was approved on August 16, 2023.

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 69 days 1,209 days or 1,773 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: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29964 Filed 12–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0119]

Fiscal Year 2025 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled ''FY 2025 Generic Drug Science and Research Initiatives Workshop.'' The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of interested parties—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2022 (GDUFA III) to develop an annual list of science and research initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2026 Generic Drug User Fee Amendments (GDUFA) science and research initiatives.

DATES: The public workshop will be held on June 3 and 4, 2025. Either electronic or written comments on this public workshop must be submitted by July 7, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in person and will be accessible virtually. Registrants will have an opportunity to indicate their interest in attending the public workshop in person. If there are restrictions imposed by applicable health guidelines for in-person gatherings, or seating capacity limitations, registrants interested in attending the public workshop in person will be contacted. The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security Information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

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 July 7, 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–2023–N–0119 for ''FY 2025 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments.'' Received comments,