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,

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: Sam Raney, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993, 240–402–7967, *Sameersingh.Raney@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240–402–7957, *Robert.Lionberger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112–144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I commitment letter) to work with industry and interested parties on identifying science and research initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA was reauthorized until September 2022 through the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115–52), and in September 2022, GDUFA was reauthorized until September 2027 through GDUFA III (Pub. L. 117–180, 136 Stat. 2155). In the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III commitment letter),[1] FDA agreed to conduct annual public workshops to solicit input from industry and interested parties for inclusion in an annual list of GDUFA III regulatory science initiatives. This public workshop scheduled for June 3 and 4, 2025, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of this public workshop is to obtain input from industry and other interested parties on identifying generic drug science and research initiatives for FY 2026. FDA is interested in receiving input about regulatory science initiatives for the ongoing years of the GDUFA III science and research program, and particularly for FY 2026.

Topics discussed during the workshop will focus on research that is needed to address scientific knowledge gaps and associated challenges impacting the development and regulatory assessment of generic products, including complex generics. As examples, topics discussed will likely focus on identifying what research is needed to clarify technical details related to implementing bioequivalence approaches recommended in FDA guidances for generic products with complex active ingredients and associated challenges (*e.g.,* related to immunogenicity), or for those that are complex products (*e.g.,* drug-device combination products), or for other generic products where research could address scientific uncertainties and, thereby, facilitate a more efficient approval pathway (*e.g.,* a waiver of in vivo bioequivalence studies for solid oral dosage forms that currently do not have proper alternative methods to support such waivers). Additional topics that can enhance public access to high-quality, safe, and effective generic products may also be discussed. Specific presentations and discussions at this workshop will be announced at a later date and may differ from the topics above. Input about the topics above will help the Agency identify and expand its scientific focus for the next fiscal year.

FDA will consider all comments made at this workshop or received through the docket (see **ADDRESSES**) as it develops its FY 2026 science and research initiatives. Information concerning the science and research initiatives for generic drugs can be found on the Science & Research website at *https://www.fda.gov/drugs/generic-drugs/science-research.*

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://fda.zoomgov.com/webinar/register/WN_wxxGXb5HSgKMAa2Q_sJLEw#/registration.* Registration may be performed at any time before or during the workshop. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact FDA via email at *GDUFARegulatoryScience@fda.hhs.gov* no later than 11:59 p.m. Eastern Time on May 20, 2025.

Requests for Oral Presentations: During online registration you may indicate if you wish to present your public comments and which topic(s) you wish to address. Requests to provide public comments via a prerecorded presentation or a live presentation, including in-person or virtual presentations, should be submitted via email to *GDUFARegulatoryScience@fda.hhs.gov*

[1] The GDUFA III commitment letter is available at *https://www.fda.gov/media/153631/download.*

by 11:59 p.m. Eastern Time on April 3, 2025. FDA will do its best to accommodate requests to make public comments that are within the scope of this public workshop; *i.e.,* those that identify what research is needed to address specific challenges for generic product development or regulatory assessment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the workshop. Based on the public comment presentation requests received by April 3, 2025, at 11:59 p.m. Eastern Time, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin; FDA will select and notify participants by April 30, 2025. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than May 20, 2025, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register online (as described above) to attend the workshop remotely (virtually). Registrants will receive a hyperlink that provides access to the webcast on both days. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a video recording and audio transcript of the public workshop are available, they will be accessible at *https://www.regulations.gov* or via the Science & Research FDA website accessible at *https://www.fda.gov/drugs/generic-drugs/science-research.* They may also be available for viewing at the Dockets Management Staff (see **ADDRESSES**).

Dated: December 12, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29962 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–2022–E–0681; FDA–2022–E–0682; FDA–2022–E–0683]

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

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 BYLVAY 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–2022–E–0681, FDA–2022–E–0682, and FDA–2022–E–0683 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BYLVAY.'' 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