ENVISION MAMMOGRAPHY PLATFORM 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 ENVISION MAMMOGRAPHY PLATFORM is 310 days. Of this time, 0 days occurred during the testing phase of the regulatory review period, while 310 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):* August 31, 2023. FDA has verified the applicant's claim that the premarket approval application (PMA) for ENVISION MAMMOGRAPHY PLATFORM (PMA P080003/S009) was initially submitted August 31, 2023.

3. *The date the application was approved:* July 5, 2024. FDA has verified the applicant's claim that PMA P080003/S009 was approved on July 5, 2024.

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 application for patent extension, this applicant seeks 1,163, or 1,198 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20667 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–5681]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALTIUS DIRECT ELECTRICAL NERVE STIMULATION 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 ALTIUS Direct Electrical Nerve Stimulation System and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 January 23, 2026. 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 May 26, 2026. 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 January 23, 2026. 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–2024–E–5681 for Determination of Regulatory Review Period for Purposes of Patent Extension; ALTIUS DIRECT ELECTRICAL NERVE STIMULATION 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM. ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM is indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. Subsequent to this approval, the USPTO received a patent term restoration application for ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM (U.S. Patent No. 9,295,841) from Neuros Medical, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ALTIUS DIRECT ELECTRICAL NERVE STIMULATION 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 ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM is 3,982 days. Of this time, 3,558 days occurred during the testing phase of the regulatory review period, while 424 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:* October 3, 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 October 3, 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):* June 30, 2023. FDA has verified the applicant's claim that the premarket approval application (PMA) for ALTIUS DIRECT ELECTRICAL NERVE STIMULATION SYSTEM (PMA P230020) was initially submitted June 30, 2023.

3. *The date the application was approved:* August 26, 2024. FDA has verified the applicant's claim that PMA P230020 was approved on August 26, 2024.

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 application for patent extension, this applicant seeks 1,747 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20668 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–5935]

Intercept Pharmaceuticals, Inc., et al.; Withdrawal of Approval of New Drug Application for OCALIVA (Obeticholic Acid) Tablets, 5 Milligrams and 10 Milligrams, and Three Abbreviated New Drug Applications for Obeticholic Acid Tablets, 5 Milligrams and 10 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application (NDA) for OCALIVA (obeticholic acid) tablets, 5 milligrams (mg) and 10 mg, held by Intercept Pharmaceuticals, Inc., 305 Madison Ave., Morristown, NJ 07960 (Intercept). In addition, FDA is withdrawing approval of three abbreviated new drug applications (ANDAs) for obeticholic acid tablets, 5 mg and 10 mg, from three separate ANDA holders. Intercept voluntarily requested withdrawal of its NDA, and Apotex, Inc., Lupin Limited, and MSN Laboratories Private Limited voluntarily requested withdrawal of their respective ANDAs, under § 314.150(d) (21 CFR 314.150(d)). The expedited withdrawal procedures set forth in section 506(c)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been waived.

DATES: Approval is withdrawn as of November 24, 2025.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants and their respective drugs and applications are included in the following table.

TABLE 1—NDAS AND ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 207999	OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg	Intercept Pharmaceuticals, Inc., 305 Madison Ave., Morristown, NJ 07960 (Intercept).
ANDA 214862	Obeticholic Acid tablets, 5 mg and 10 mg	Apotex Inc., c/o Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326 (Apotex).
ANDA 214980	Obeticholic Acid tablets, 5 mg and 10 mg	Lupin Limited, c/o Lupin Pharmaceuticals, Inc., 400 Campus Dr., Somerset, NJ 08873 (Lupin).
ANDA 215017	Obeticholic Acid tablets, 5 mg and 10 mg	MSN Laboratories Private Limited, c/o MSN Pharmaceuticals, Inc., 20 Duke Rd., Piscataway, NJ 08854 (MSN).

On May 27, 2016, FDA approved NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, under the accelerated approval pathway pursuant to section 506(c)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)(1) and 21 CFR 314.510). The accelerated approval of OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, for PBC, was subject to the requirement that Intercept conduct a postmarketing trial to verify and describe the clinical benefit of OCALIVA.

On May 26, 2021, FDA approved a safety labeling change to revise the indication of OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, to the treatment of adult patients with PBC without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with UDCA with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

On May 30, 2023, FDA approved the ANDAs listed in table 1 for obeticholic acid tablets, 5 mg and 10 mg, for the conditions of use in the labeling of NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, the reference listed drugs on which these ANDAs relied.

On August 27, 2025, FDA notified Intercept of a potential problem with OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, (NDA 207999), specifically that the postmarketing trial did not verify clinical benefit and that OCALIVA-treated PBC patients in the postmarketing trial who had early-stage disease at baseline had an excess of liver transplants and deaths. FDA recommended that Intercept request withdrawal of approval of the NDA 207999 products under § 314.150(d) (21 CFR 314.150(d)). FDA also requested in follow-up correspondence sent on August 28, 2025, that Intercept waive the expedited withdrawal procedures set forth in section 506(c)(3)(B) of the FD&C Act.

On October 1, 2025, FDA notified Apotex of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 214862 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.

On October 1, 2025, FDA notified Lupin of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 214980 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.

On October 3, 2025, FDA notified MSN of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 215017 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.