Categories of Individuals

The categories of individuals whose information is involved in the matching program include, but are not limited to, those individuals who have applied for Lifeline; are currently receiving Lifeline; are individuals who enable another individual in their household to qualify for Lifeline; are minors whose status qualifies a parent or guardian for Lifeline; or are individuals who have received Lifeline.

Categories of Records

The categories of records involved in the matching program include the last four digits of the applicant's Social Security Number, date of birth, first and last name. The National Verifier will transfer these data elements to the Iowa Department of Health and Human Services which will respond either ''yes'' or ''no'' that the individual is enrolled in a qualifying assistance program: SNAP administered by the Iowa Department of Health and Human Services.

System(s) of Records

The records shared as part of this matching program reside in the Lifeline system of records, FCC/WCB–1, Lifeline, which was published in the **Federal Register** at 91 FR 9251 (Feb. 25, 2026).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2026–16266 Filed 8–7–26; 8:45 am]

BILLING CODE 6712–01–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 108062026–1111–01]

Notice of Council Updated NEPA Procedures

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice.

SUMMARY: The Gulf Coast Ecosystem Restoration Council (Council) has updated its procedures (NEPA Procedures) for implementing the National Environmental Policy Act (NEPA). The Council's updated NEPA Procedures are available at *www.restorethegulf.gov.*

FOR FURTHER INFORMATION CONTACT: Please send questions by email to John Ettinger by email *john.ettinger@restorethegulf.gov* or telephone (504) 444–3522.

SUPPLEMENTARY INFORMATION: On May 5, 2015, the Council issued its NEPA Procedures (80 FR 25680). The Council's 2015 NEPA Procedures were based on the Council on Environmental Quality (CEQ) NEPA regulations at 40 CFR parts 1500–1508. On January 8, 2026, CEQ issued a final rule removing these regulations (91 FR 618) in accord with Executive Order (E.O.) 14154, *Unleashing American Energy* (January 20, 2025). E.O. 14154 further directed agencies to revise their NEPA implementing procedures consistent with the E.O. Accordingly, the Council has revised its NEPA Procedures. As part of the revision process the Council eliminated a Categorical Exclusion for administrative and routine office activities, which do not meet the definition of major Federal action. The Council's updated NEPA Procedures can be found at *www.restorethegulf.gov.*

Keala J. Hughes,

Director of External Affairs & Tribal Relations, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2026–16267 Filed 8–7–26; 8:45 am]

BILLING CODE 6560–58–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–6298]

Determination That OZOBAX (Baclofen) Oral Solution, 5 Milligrams/5 Milliliters Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that OZOBAX (baclofen) oral solution, 5 milligrams (mg)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6269, Silver Spring, MD 20993–0002, 301–796–3600, *heather.dorsey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

OZOBAX (baclofen) oral solution, 5 mg/5 mL, is the subject of NDA 208193, held by Metacel Pharmaceuticals LLC, and initially approved on September 18, 2019. OZOBAX is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

In a letter dated October 13, 2023, Metacel Pharmaceuticals LLC notified FDA that OZOBAX (baclofen) oral solution, 5 mg/5 mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Novitium Pharma LLC submitted a citizen petition dated June 2, 2026 (Docket No. FDA–2026–P–6298), under 21 CFR 10.30, requesting that the Agency determine whether OZOBAX (baclofen) oral solution, 5 mg/5 mL, was

withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that OZOBAX (baclofen) oral solution, 5 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting OZOBAX (baclofen) oral solution, 5 mg/5 mL was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of OZOBAX (baclofen) oral solution, 5 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list OZOBAX (baclofen) oral solution, 5 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16248 Filed 8–7–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–E–5206]

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

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 BRINSUPRI 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 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 October 9, 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 February 8, 2027. 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 October 9, 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–2025–E–5206 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BRINSUPRI.'' 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://*