

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.

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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.*

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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