

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2025-P-1021]

**Determination That EPINEPHRINE (Epinephrine) Solution, 1 Milligram/Milliliter, Prefilled Syringe for Intravenous Use, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.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 or Agency) has determined that EPINEPHRINE (epinephrine) solution, 1 milligram (mg)/milliliter (mL), prefilled syringe for intravenous use, was not withdrawn from sale for reasons of safety or effectiveness.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:**

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, [Stacy.Kane@fda.hhs.gov](mailto:Stacy.Kane@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approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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 (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, is the subject of NDA 205029, held by BPI Labs, LLC. The NDA was initially approved on July 29, 2014. EPINEPHRINE is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

In a letter dated May 29, 2024, BPI Labs, LLC notified FDA that EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Alembic Pharmaceuticals Ltd. submitted a citizen petition dated March 29, 2025 (Docket No. FDA-2025-P-1021), under 21 CFR 10.30, requesting that the Agency determine whether EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, 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 EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have

found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list EPINEPHRINE (epinephrine) solution, 1 mg/mL, prefilled syringe for intravenous use, 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.

Dated: May 23, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-09901 Filed 5-30-25; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of an Exclusive Patent License: Exceptionally Selective D2 Dopamine Receptor Antagonists as Therapeutics**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Neurological Disorders and Stroke and the National Center for Advancing Translational Sciences, institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Psycala Bio, Inc. (Psycala), incorporated in Delaware.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Neurological Disorders and Stroke Technology Transfer on or before July 17, 2025 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Susan Ano, Ph.D., Chief, Technology Transfer Branch, Telephone: 301-435-5515; Email: [susan.ano@nih.gov](mailto:susan.ano@nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

“2,4-Diphenyl-3,4-Dihydroquinazoline Derivatives and Related Compounds as D2 Dopamine Receptor-Selective Antagonists”.

U.S. Patent Application No. 63/666,563, filed July 1, 2024 (HHS Reference E-119-2021-0-US-01).

The patent rights in this invention have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

NCGC-1360 ((s)-4-(6-chloro-2-(5-methoxy-pyridin-2-yl)-4-phenylquinazolin-3(4h)-yl)-2-methylbutan-2-ol) and related analogs for the treatment of central nervous system disorders, including but not limited to schizophrenia spectrum and other psychotic disorders, bipolar disorder and related disorders, and depressive disorders as classified by the Diagnostic and Statistical Manual of Mental Disorders (DSM V).

Researchers at NINDS and NCATS have developed a new class of therapeutic agents that may significantly advance the treatment of CNS disorders. These compounds are antagonists with high selectivity for the dopamine D2 receptor (D2R), showing over 1,000-fold selectivity compared to D3R and D4R. Promising in vitro ADME (Absorption, Distribution, Metabolism, and Excretion) data and in vivo pharmacokinetics indicate effective brain penetration, positioning these molecules as potential treatments for schizophrenia, bipolar disorder, and depression. Designed to minimize off-target side effects, particularly extrapyramidal motor side effects (EPS), these compounds maintain therapeutic efficacy. These compounds exhibit atypical antipsychotic properties without typical off-target effects and are expected to have reduced overall side effects. These molecules can be administered in various pharmaceutical forms, either alone or in combination with other therapeutic agents.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within forty-five (45) days from the date of this published Notice, the National

Institute of Neurological Disorders and Stroke receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

**Susan E. Ano,**

*Chief, Technology Transfer Branch, National Institute of Neurological Disorders and Stroke.*

[FR Doc. 2025-09844 Filed 5-30-25; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Social and Community Influences on Health Integrated Review Group; Social Psychology, Personality and Interpersonal Processes Study Section.

*Date:* June 26–27, 2025.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Joshua J. Matacotta, PSYD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-7498, [josh.matacotta@nih.gov](mailto:josh.matacotta@nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Environmental Determinants of Disease Study Section.

*Date:* June 30–July 1, 2025.

*Time:* 8:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Stacey Nicole Williams, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, [stacey.williams@nih.gov](mailto:stacey.williams@nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group; Basic Cancer Immunobiology Study Section.

*Date:* June 30–July 1, 2025.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301-402-4788, [sarita.sastry@nih.gov](mailto:sarita.sastry@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Sensory and Motor Neurosciences, Cognition and Perception.

*Date:* June 30–July 1, 2025.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Melanie Marie Pina, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-0718, [melanie.pina@nih.gov](mailto:melanie.pina@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Projects: National Center for Biomedical Imaging and Bioengineering.

*Date:* June 30–July 2, 2025.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Tianhong Wang, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 435-11889, [wangt3@mail.nih.gov](mailto:wangt3@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member