DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12541]

Determination That DIBENZYLINE (Phenoxybenzamine Hydrochloride) Oral Capsule, 10 Milligrams, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products 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.*

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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in table 1 are no longer being marketed.

TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 008708	DIBENZYLINE	Phenoxybenzamine Hydrochloride.	10 Milligrams (mg)	Capsule; Oral	Advanz Pharma (US).
NDA 018701	HALDOL	Haloperidol Decanoate	Equivalent to (EQ) 50 mg Base/mL; EQ 100 mg Base/mL.	Injectable; Injection	Janssen Pharmaceuticals, Inc.
NDA 018859	VIRAZOLE	Ribavirin	6 Grams (g)/Vial	For Solution; Inhalation	Bausch Health US, LLC.
NDA 019557	VEPESID	Etoposide	100 mg	Capsule; Oral	Onesource Specialty Private Limited.
NDA 019901	ALTACE	Ramipril	1.25 mg; 2.5 mg; 5 mg; 10 mg.	Capsule; Oral	King Pharmaceuticals LLC.
NDA 020572	BUPHENYL	Sodium Phenylbutyrate	500 mg	Tablet; Oral	Horizon Therapeutics US Holding LLC.
NDA 020859	SONATA	Zaleplon	5 mg; 10 mg	Capsule; Oral	Pfizer, Inc.
NDA 020862	HECTOROL	Doxercalciferol	0.5 Micrograms (mcg); 1 mcg; 2.5 mcg.	Capsule; Oral	Sanofi Genzyme.
NDA 021773	BYETTA	Exenatide Synthetic	300 mcg/1.2 mL (250 mcg/mL); 600 mcg/2.4 mL (250 mcg/mL).	Injectable; Subcutaneous	AstraZeneca AB.
NDA 021912	BROVANA	Arformoterol Tartrate	EQ 0.015 mg base/2 mL	Solution; Inhalation	Lupin, Inc.
NDA 022206	RAPAFLO	Silodosin	4 mg; 8 mg	Capsule; Oral	Abbvie, Inc.
NDA 022328	INTERMEZZO	Zolpidem Tartrate	1.75 mg; 3.5 mg	Tablet; Sublingual	Purdue Pharma Products LP.
ANDA 087440	DEXAMETHASONE SODIUM PHOSPHATE.	Dexamethasone Sodium Phosphate.	EQ 4 mg phosphate/mL	Injectable; Injection	Luitpold Pharmaceuticals, Inc.
NDA 202133	FLUOXETINE HYDROCHLORIDE.	Fluoxetine Hydrochloride	EQ 60 mg Base	Tablet; Oral	TWI Pharmaceuticals, Inc.
NDA 205596	NO_XAFIL	Posaconazole	300 mg/16.7 mL (18 mg/mL)	Solution; Intravenous	Merck Sharp and Dohme Corp.
NDA 211996	VYNDAQEL	Tafamidis Meglumine	20 mg	Capsule; Oral	Foldrx Pharmaceuticals, LLC, A Wholly Owned Sub. of Pfizer, Inc.
NDA 022186	AK-FLUOR 25%	Fluorescein Sodium	EQ 500 mg Base/2 mL (EQ 250 mg Base/mL).	Injectable; Intravenous	Long Grove Pharmaceuticals, LLC.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug

products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products 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. 2026–23141 Filed 11–12–26; 8:45 am]

BILLING CODE 4164–01–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: Center for Scientific Review Special Emphasis Panel; ALACRITY Research Centers (P50).

Date: December 4, 2026.

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: Sandhya Sanghi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3393, *sandhya.sanghi@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–25–446: Development of Interventions to Prevent and Treat Substance Use Disorders and Overdose.

Date: December 4, 2026.

Time: 10:00 a.m. to 9:00 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: Brian Hoshaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–496–1486, *hoshawb@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Motivated Behavior and Neurotoxicology of Addictive Substances.

Date: December 4, 2026.

Time: 10:00 a.m. to 9:00 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: Mamatha Garige, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 443–1706, *mamatha.garige@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in Therapeutics Delivery.

Date: December 4, 2026.

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: John Grason, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443–8416, *john.grason@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bacterial-Host Interactions and Immunity and Host Defense.

Date: December 4, 2026.

Time: 11:00 a.m. to 4:00 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: Irene Ramos Lopez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4891, *irene.ramoslopez@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Transmission of Vector-Borne and Zoonotic Diseases.

Date: December 4, 2026.

Time: 1:00 p.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: Haruhiko Murata, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3245, *muratah@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 9, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–23129 Filed 11–12–26; 8:45 am]

BILLING CODE 4167–05–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.

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Name of Committee: Center for Scientific Review Special Emphasis Panel; Radiological or Nuclear Medical Countermeasure Product Development Support (PDS).

Date: December 1, 2026.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

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

Meeting Format: Virtual Meeting.

Contact Person: Thomas F. Conway, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–9085, *chiuc@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Health Technology and Methodologies.