DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5817]

Determination That Protamine Sulfate (Protamine Sulfate) Intravenous; Solution, 50 Milligrams/5 Milliliters, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily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 006460	PROTAMINE SULFATE	Protamine Sulfate	50 Milligrams (mg)/5 Milliliters (mL) (10 mg/mL).	Solution; Intravenous	Eli Lilly and Co.
NDA 011719	METHOTREXATE SODIUM; METHOTREXTATE LPF AND METHOTREXATE PRESERVATIVE FREE.	Methotrexate Sodium	Equal to (EQ) 2.5 mg Base/mL; EQ 20 mg Base/2 mL (EQ 10 mg Base/mL); EQ 20 mg Base/Vial; EQ 25 mg Base/mL; EQ 25 mg Base/mL; EQ 2.5 grams (g) Base/100 mL (EQ 25 mg Base/mL); EQ 50 mg Base/Vial; EQ 100 mg Base/Vial; EQ 1g Base/Vial.	Injectable; Injection	Hospira, Inc.
NDA 012250	CARBOCAINE	Mepivacaine Hydrochloride.	1%; 1.5%; 2%	Injectable; Injection	Hospira, Inc.
NDA 016909	LIDEX	Fluocinonide	0.05%	Ointment; Topical	Alvogen, Inc.
NDA 017010	DESONIDE	Desonide	0.05%	Cream; Topical	Padagis LLC.
NDA 017735	MODICON 28	Ethinyl Estradiol; Norethindrone.	0.035 mg; 0.5 mg	Tablet; Oral-28	Janssen Pharmaceuticals, Inc.
NDA 018337	ACETAMINOPHEN	Acetaminophen	650 mg	Suppository; Rectal	Taro Pharmaceutical Industries Ltd.
NDA 019260	PSORCON	Diflorasone Diacetate	0.05%	Ointment; Topical	Pfizer Inc.
NDA 019487 P001	IMODIUM A-D	Loperamide Hydrochloride.	1 mg/5 mL	Solution; Oral	Kenvue Brands LLC.
NDA 020021	SUDAFED 24 HOUR	Pseudoephedrine Hydrochloride.	240 mg	Tablet, Extended Release; Oral.	Kenvue Brands LLC.
NDA 020449	TAXOTERE	Docetaxel	20 mg/mL (20 mg/mL); 80 mg/4 mL (20 mg/mL).	Injectable; Injection	Sanofi-Aventis U.S. LLC.
NDA 020497	FARESTON	Toremifene Citrate	EQ 60 mg Base	Tablet; Oral	Kyowa Kirin.
NDA 020657	SPORANOX	Itraconazole	10 mg/mL	Solution; Oral	Janssen Pharmaceuticals.
NDA 020710	PAXIL	Paroxetine Hydrochloride.	EQ 10 mg Base/5 mL	Suspension; Oral	Apotex Inc.
NDA 020747	ACTIQ	Fentanyl Citrate	EQ 0.2 mg Base; EQ 0.4 mg Base; EQ 0.6 mg Base; eq 0.8 mg Base; EQ 1.2 mg Base; EQ 1.6 mg Base.	Troche/Lozenge; Transmucosal.	Cephalon, LLC.
NDA 020757	AVAPRO	Irbesartan	75 mg	Tablet; Oral	Sanofi-Aventis U.S. LLC.
NDA 021065	FEMHRT	Ethinyl Estradiol; Norethindrone Acetate.	0.0025 mg; 0.5 mg	Tablet; Oral	Allergan Pharmaceuticals International Ltd.
NDA 021087	TAMIFLU	Oseltamivir Phosphate	EQ 30 mg Base; EQ 45 mg Base	Capsule; Oral	Roche.

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

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021227	CANCIDAS	Caspofungin Acetate	50 mg/Vial; 70 mg/Vial	Powder; Intravenous	Merck Sharp & Dohme.
NDA 021506	MYCAMINE	Micafungin Sodium	EQ 50 mg Base/Vial; EQ 100 mg Base/Vial.	Injectable; Intravenous	Astellas Pharma US Inc.
NDA 021520	SYMBYAX	Fluoxetine Hydrochloride; Olanzapine.	EQ 25 mg Base; EQ 3 mg Base; EQ 25 mg Base; EQ 6 mg Base; EQ 25 mg Base; EQ 12 mg Base; EQ 50 mg Base; EQ 6 mg Base; EQ 50 mg Base; EQ 12 mg Base.	Capsule; Oral	Eli Lilly and Co.
NDA 021947	FENTORA	Fentanyl Citrate	EQ 0.1 mg Base; EQ 0.2 mg Base; EQ 0.4 mg Base; EQ 0.6 mg Base; EQ 0.8 mg Base.	Tablet; Buccal, Sublingual.	Cephalon, LLC.
NDA 022076	LOCOID	Hydrocortisone Butyrate	0.1%	Lotion; Topical	Bausch Health.
NDA 022116	LEXIVA	Fosamprenavir Calcium	EQ 50 mg Base/mL	Suspension; Oral	ViiV Healthcare.
NDA 022224	TRILIPIX	Choline Fenofibrate	EQ 45 mg Fenofibric Acid; EQ 135 mg Fenofibric Acid.	Capsule, Delayed Release; Oral.	AbbVie Inc.
NDA 022525	NAMENDA XR	Memantine Hydrochloride.	14 mg; 21 mg; 28 mg	Capsule, Extended Release; Oral.	AbbVie Inc.
NDA 022573	NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE.	Ethinyl Estradiol; Norethindrone.	0.025 mg; 0.8 mg	Tablet, Chewable; Oral	Teva Branded Pharmaceutical Products R&D, Inc.
NDA 050007	VIBRAMYCIN	Doxycycline Hyclate	EQ 100 mg Base	Capsule; Oral	Pfizer, Inc.
NDA 050537	CLEOCIN	Clindamycin Phosphate	EQ 1% Base	Swab; Topical	Pfizer, Inc.
ANDA 080615	DIMENHYDRINATE	Dimenhydrinate	50 mg/mL	Injectable; Injection.	
ANDA 084499	ESTRACE	Estradiol	1 mg	Tablet; Oral	Bristol Myers Squibb.
ANDA 084500	ESTRACE	Estradiol	2 mg	Tablet; Oral	Bristol Myers Squibb.
ANDA 088023	ADIPEX–P	Phentermine Hydrochloride.	37.5 mg	Capsule; Oral	Teva USA.
NDA 204300	VAZCULEP	Phenylephrine Hydrochloride.	10 mg/mL (10 mg/mL); 50 mg/5 mL; 100 mg/10 mL.	Solution; Intravenous	Exela Pharma Sciences.
NDA 204412	DELZICOL	Mesalamine	400 mg	Capsule, Delayed Release; Oral.	AbbVie Inc.
NDA 208418	CALCIUM GLUCONATE	Calcium Gluconate	1 g/50 mL; 2 g/100mL	Solution; Intravenous	Fresenius Kabi USA, LLC.
NDA 209091	QTERN	Dapagliflozin; Saxagliptin Hydrochloride.	5 mg; EQ 5 mg Base 10 mg; EQ 5 mg Base.	Tablet; Oral	AstraZeneca AB.

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. 2026–11429 Filed 6–5–26; 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; Career Development Training.

Date: July 7, 2026.

Time: 9:00 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: Tushar Baran Deb, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Rockville, MD 20850, (240) 276–6132, *tushar.deb@nih.gov*.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Bacterial Virulence Study Section.

Date: July 7–8, 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: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; NIDCD Clinical Research Center Grant (P50) Review.

Date: July 7, 2026.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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