

Application No.	Drug	Applicant
NDA 020037	Voltaren (diclofenac sodium) Ophthalmic Solution, 0.1%	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936-1080.
NDA 021169	Razadyne (galantamine hydrobromide) Tablets, EQ 4 mg base, EQ 8 mg base, and EQ 12 mg base.	Janssen Research & Development, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021204	Starlix (nateglinide) Tablets, 60 mg, and 120 mg	Novartis Pharmaceuticals Corp.
NDA 021406	Fortical (calcitonin-salmon recombinant) Nasal Spray, 200 International Units/Spray.	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
NDA 021860	Sarafem (fluoxetine HCl) Tablets, EQ 10 mg base, EQ 15 mg base, and EQ 20 mg base.	Allergan Pharmaceuticals International Ltd., c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 202833	Picato (ingenol mebutate) Gel, 0.015%, and 0.05%	LEO Laboratories Ltd., c/o LEO Pharma Inc., 7 Giralda Farms, Madison, NJ 07940.
NDA 202880	Zohydro ER (hydrocodone bitartrate) Extended-release Capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg.	Recro Gainesville LLC, 1300 Gould Dr., Gainesville, GA 30504.
NDA 204683	Khedeza (desvenlafaxine) Extended-Release Tablets, 50 mg, and 100 mg.	Osmotica Pharmaceutical US LLC, 400 Crossing Blvd., Bridgewater, NJ 08807.
NDA 207916	Cetylev (acetylcysteine) Effervescent Tablets, 500 mg, and 2.5 g.	Arbor Pharmaceuticals, LLC, 6 Concourse Pkwy., Suite 1800, Atlanta, GA 30328.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 4, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 4, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-02059 Filed 2-1-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0074]

Watson Laboratories, Inc., et al.; Withdrawal of Approval of Eight Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of eight abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 4, 2022.

FOR FURTHER INFORMATION CONTACT:

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 075152	Diclofenac Potassium Tablets, 50 milligrams (mg)	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 091376	Topotecan Hydrochloride (HCl) for Injection, Equivalent to (EQ) 4 mg base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 091471	Efavirenz Tablets, 600 mg	Mylan Pharmaceuticals Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505.
ANDA 200463	Itraconazole Capsules, 100 mg	Mylan Pharmaceuticals Inc., a Viatris Company, 781 Chestnut Ridge Rd., Morgantown, WV 26504.
ANDA 202395	Ziprasidone HCl Capsules, EQ 20 mg base, EQ 40 mg base, EQ 60 mg base, and EQ 80 mg base.	Do.
ANDA 203170	Docetaxel Injection, 40 mg/milliliter	Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, eVenus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540.
ANDA 203574	Mesalamine Delayed Release Tablets, 1.2 grams	Mylan Pharmaceuticals Inc., a Viatris Company, 781 Chestnut Ridge Rd., Morgantown, WV 26504.
ANDA 208177	Atazanavir Sulfate Capsules, EQ 150 mg base, EQ 200 mg base, and EQ 300 mg base.	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 4, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 4, 2022 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-02053 Filed 2-1-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting is devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine and will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: June 23–24, 2022.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: Virtual Meeting.

Contact Person: Dianne Babski, Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Building 38, Room 4S404, Bethesda, MD 20894, 301-827-4729, babskid@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: January 28, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-02128 Filed 2-1-22; 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 10(d) 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: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Guided Interventions and Surgery Study Section.

Date: March 3–4, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435-1195, Chengy5@csr.nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; Drug Discovery and Molecular Pharmacology Study Section.

Date: March 3–4, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeffrey Smiley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-594-7945, smileyja@csr.nih.gov.

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

Fellowships: Chemistry, Biochemistry and Biophysics A.

Date: March 3, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-4390, shan.wang@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hypersensitivity, Allergies and Mucosal Immunology (HAMI).

Date: March 3–4, 2022.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Deborah Hodge, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4207, MSC 7812, Bethesda, MD 20892, (301) 435-1238, hodged@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA/REAP: Cardiovascular and Respiratory Sciences.

Date: March 3, 2022.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301-435-0904, sara.ahlgren@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Antiviral Drug Discovery and Mechanisms of Resistance.

Date: March 7–8, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-402-9448, shinako.takada@nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions Study Section.

Date: March 7–8, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.