DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1866]

Wockhardt Ltd., et al.; Withdrawal of Approval of Nine 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 nine 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 9, 2020.

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 040533	Bethanechol Chloride Tablets, 10 milligrams (mg)	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, 6451 Main St., Morton Grove, IL 60053.
ANDA 040534	Bethanechol Chloride Tablets, 25 mg	Do.
ANDA 075015	Acyclovir Sodium for Injection, Equivalent to (EQ) 500 mg base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 075773	Pamidronate Disodium for Injection, 30 mg/vial, and 90 mg/vial.	Do.
ANDA 076206	Calcitriol Injection, 0.001 mg/milliliter (mL)	Rockwell Medical, Inc., 30142 S. Wixom Rd., Wixom, MI 48393.
ANDA 076207	Pamidronate Disodium Injection, 30 mg/10 mL (3 mg/mL) and 90 mg/mL (9 mg/mL).	Fresenius Kabi USA, LLC.
ANDA 077788	Albuterol Sulfate Syrup, EQ 2 mg base/5 mL	VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771.
ANDA 077990	Zolpidem Tartrate Tablets, 5 mg and 10 mg	Carlsbad Technology, Inc., U.S. Agent for Yung Shin Pharmaceutical Industrial Co., Ltd., 4761 Tara Ct., West Bloomfield, MI 48323.
ANDA 202410	Donepezil Hydrochloride Tablets, 23 mg	Hisun Pharmaceutical (Hangzhou) Co., Ltd., U.S. Agent, Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd floor, Bridgewater, NJ 08807.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2020. 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 November 9, 2020 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: October 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22403 Filed 10–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1867]

Novartis Pharmaceuticals Corp., et al.; Withdrawal of Approval of 13 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 13 new drug applications (NDAs) 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 November 9, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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
NDA 003290	Neo-Calglucon (calcium glubionate) Syrup	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 009816	Cortef Acetate S.E.E. Drops (hydrocortisone acetate) Ophthalmic Solution.	Upjohn, a Pfizer Division, 235 East 42nd St., New York, NY 10017.
NDA 009817	Cortef Acetate (hydrocortisone acetate) Ophthalmic Ointment, 1.5%.	Do.
NDA 010645	Optef Drops (hydrocortisone probutate) Ophthalmic Solution, 0.2%.	Do.
NDA 010155	Mytelase (ambenonium chloride) Tablets, 10 milligrams (mg).	Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 016659	Norinyl 1 + 50 (norethindrone and mestranol) Tablets, 1 mg/0.05 mg.	Actavis Laboratories Ut, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 41 Moores Rd., Frazer, PA 19355.
NDA 016807	Thyrolar (liotrix [tetraiodothyronine levothyroxine sodium (T4) and triiodothyronine liothyronine sodium (T3)]) Tablets, 0.0125 mg/0.0031 mg, 0.025 mg/0.0063 mg, 0.05 mg/0.0125 mg, 0.1 mg/0.025 mg, 0.15 mg/0.0375 mg, and 0.25 mg/0.0625 mg.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 017919	Ortho Novum 1/35 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/1 mg.	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 018768	VePesid (etoposide) Injection, 20 mg/mL	Corden Pharma Latina S.p.A., c/o Clinipace Inc., 1434 Spruce St., Suite 100, Boulder, CO 80302.
NDA 019972	Ocupress (carteolol hydrochloride) Ophthalmic Solution, 1%.	Novartis Pharmaceuticals Corp.
NDA 021590	FazaClo (clozapine) Orally Disintegrating Tablets, 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg.	Jazz Pharmaceuticals Ireland Ltd., c/o Jazz Pharmaceuticals, Inc., 3170 Porter Dr., Palo Alto, CA 94304.
NDA 021664	Bromday/Xibrom (bromfenac) Ophthalmic Solution, Equivalent to 0.09%.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 022018	Lamivudine and Zidovudine Tablets, 150 mg lamivudine and 300 mg zidovudine.	Pharmacare Ltd., c/o Lachman Consultants Services, Inc., 1600 Stewart Ave., Suite 604, Westbury, NY 11590.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2020. 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 November 9, 2020 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: October 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22402 Filed 10–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; Jointly Sponsored Predoctoral Training Program in the Neurosciences (T32).

Date: November 2, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; y BRAIN Initiative: Secondary Analysis and Archiving of BRAIN Initiative Data (R01).

Date: November 5, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)