will take respondents, collectively, 1,080 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information, including identifying prior FDA submissions for the product or relevant versions of the product, that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 1,680 hours (600 hours to prepare and submit meeting requests and 1,080 hours to prepare and submit information packages). Our estimated burden for the information collection reflects an overall decrease of 644 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years and our projections for the next 3 years.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02055 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–0079]

Hikma Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 4, 2022.

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 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 006134	Dolophine (methadone hydrochloride (HCl)) Tablets, 5 milligrams (mg), and 10 mg. Dolophine (methadone HCl) Syrup, 10 mg/30 milliliter (mL).	Hikma Pharmaceuticals USA, Inc., 1809 Wilson Rd., Columbus, OH 43228.
NDA 006882	Phisohex (hexachlorophene) Emulsion, 3%	Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 009818	Kemadrin (procyclidine HCl) Tablets, 2 mg, and 5 mg	Monarch Pharmaceuticals, LLC, c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 012301	Librium (chlordiazepoxide HCl), Injection, 100 mg/ampule.	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 013416	Norgesic (orphenadrine citrate, aspirin, and caffeine) Tablets, 25 mg/385 mg/30 mg. Norgesic Forte (orphenadrine citrate, aspirin, and caffeine) Tablets, 50 mg/770 mg/60 mg.	Bausch Health US, LLC.
NDA 014228	Spandin (aspirin and sodium salicylate) Time-released Tablets, 7.5 grains/2.5 grains.	Abbott Healthcare Pvt. Ltd., c/o G&L Scientific, Independence Blvd., 4th Floor, Warren, NJ 07059.
NDA 016194	Talwin (pentazocine lactate) Injection, equivalent to (EQ) 30 mg base/mL.	Hospira Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
NDA 016418	Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg.	Wyeth Pharmaceuticals LLC, 235 E. 42nd St., New York, NY 10017.
NDA 016704	Resectisol (mannitol) Irrigation Solution, 5 grams (g)/100 mL.	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 016762	Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg.	Wyeth Pharmaceuticals LLC.
NDA 016954	Micronor (norethindrone) Tablets, 0.35 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 017013	Sodium Chloride Injection, 20 g/100 mL	Abbott Healthcare Pvt. Ltd., c/o G&L Scientific.
NDA 017683	Inderal (propranolol HCL) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg.	Wyeth Pharmaceuticals LLC.
NDA 018423	Hibiclens (chlorhexidine gluconate) Sponge, 4%	Mölnlycke Health Care, 5445 Triangle Pkwy., Suite 400, Peachtree Corners, GA 30092.
NDA 018703	Zantac (ranitidine HCl) Tablets, EQ 150 mg base, and EQ 300 mg base.	GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline, 5 Crescent Dr., Philadelphia, PA 19112.
NDA 019387	Profenal (suprofen) Ophthalmic Solution, 1%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134–2099.
NDA 019530	Ucephan (sodium benzoate and sodium phenylacetate) Solution, 100 mg/mL; 100 mg/mL.	B. Braun Medical Inc.
NDA 019675	Zantac (ranitidine HCl) Syrup, EQ 15 mg base/mL	GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline.
NDA 019814	Betagan (levobunolol HCl) Ophthalmic Solution, 0.25%	Allergan, Inc.
NDA 019927	Nizoral (ketoconazole) Shampoo, 2%	Janssen Pharmaceuticals, Inc.

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	Khedezla (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.