



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2022-N-1728]**

**AbbVie Inc., et al.; Withdrawal of Approval of 30 New Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 30 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**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](mailto: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 005856	Tridione (trimethadione) Tablets, 150 milligrams (mg) Tridione (trimethadione) Capsules, 300 mg Tridione (trimethadione) Oral Solution, 200 mg/5 milliliters (mL)	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064
NDA 010679	Cantil (mepenzolate bromide) Tablets, 25 mg Cantil (mepenzolate bromide) Solution, 25 mg/5 mL	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807
NDA 016042	Dyazide (hydrochlorothiazide/triamterene) Capsules, 25 mg/37.5 mg and 25 mg/50 mg	GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112
NDA 017531	Tigan (trimethobenzamide hydrochloride (HCl)) Capsules, 300 mg	King Pharmaceuticals LLC, 235 East 42nd St., New York, NY 10017
NDA 017565	Norinyl 1+ 35 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/1 mg	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940
NDA 017766	NephrAmine 5.4% (amino acids) Injection, 5.4% (5.4 grams (g)/100 mL)	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109
NDA 018053	Bupivacaine HCl Injection, 0.25%, 0.5%, and 0.75%	Hospira, Inc., 275 North Field Dr., Bldg. H1-3S, Lake Forest, IL 60045
NDA 019558	Prinivil (lisinopril) Tablets, 2.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889-0100
NDA 019805	Heparin Sodium in 5% Dextrose Injection, 4,000 Units/100 mL and 5,000 Units/100 mL	Hospira, Inc.
NDA 019813	Duragesic (fentanyl transdermal system) Extended-release Film, 12.5 micrograms (mcg)/hour, 25 mcg/hour, 37.5 mcg/hour, 50 mcg/hour, 75 mcg/hour, and 100 mcg/hour	Janssen Research & Development, LLC, 1000 U.S. Route 202, Raritan, NJ 08869
NDA 019917	Morphine Sulfate Injection, 0.5 mg/mL	ICU Medical, Inc., 600 N. Field Dr., Lake Forest, IL 60045
NDA 020156	Videx (didanosine) Powder for Oral Solution, 10 mg/mL	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000

NDA 020570	Quadramet (samarium sm 153 lexicidronam pentasodium) Injection, 50 millicuries/mL	Lantheus Medical Imaging, Inc., 331 Treble Cove Rd., Bldg. 300-2, North Billerica, MA 01862
NDA 020591	Tarka (trandolapril and verapamil HCl) Extended-release Tablets, 1 mg/240 mg, 2 mg/180 mg, 2 mg/240 mg, and 4 mg/240 mg	AbbVie Inc.
NDA 020658	Requip (ropinirole HCl) Tablets, equivalent to (EQ) 0.25 mg base, EQ 0.5 mg base, EQ 1 mg base, EQ 2 mg base, EQ 3 mg base, EQ 4 mg base, and EQ 5 mg base	GlaxoSmithKline LLC
NDA 020685	Crixivan (indinavir sulfate) Capsules, EQ 100 mg base, EQ 200 mg base, EQ 333 mg base, and EQ 400 mg base	Merck Sharp & Dohme Corp.
NDA 020732	Subutex (buprenorphine HCl), sublingual tablets, EQ 2mg base and EQ 8mg base	Indivior Inc., 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235
NDA 020733	Suboxone (buprenorphine HCl and naloxone HCl) Sublingual Tablets, EQ 2 mg base/EQ 0.5 mg base, and EQ 8 mg base/EQ 2 mg base	Do.
NDA 020946	Preven Emergency Contraceptive Kit (ethinyl estradiol and levonorgestrel) Tablets, 0.05 mg/0.25 mg	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380
NDA 021183	Videx EC (didanosine) Delayed-release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg	Bristol-Myers Squibb Co.
NDA 021627	Namenda (memantine HCl) Oral Solution, 2 mg/mL	Allergan Sales, LLC
NDA 022008	Requip XL (ropinirole HCl) Extended-release Tablets, EQ 2 mg base, EQ 3 mg base, EQ 4 mg base, EQ 6 mg base, EQ 8 mg base, and EQ 12 mg base	GlaxoSmithKline LLC
NDA 022205	Giazo (balsalazide disodium) Tablets, 1.1 g	Salix Pharmaceuticals, Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807
NDA 022246	Metozolv ODT (metoclopramide HCl) Orally Disintegrating Tablets, EQ 5 mg base and EQ 10 mg base	Do.

NDA 022401	Twynsta (amlodipine besylate and telmisartan) Tablets, EQ 5 mg base/40 mg, EQ 5 mg base/80 mg, EQ 10 mg base/40 mg, and EQ 10 mg base/80 mg	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877
NDA 050662	Biaxin Filmtab (clarithromycin) Tablets, 250 mg and 500 mg	AbbVie Inc.
NDA 050698	Biaxin Granules for Oral Suspension (clarithromycin) 125 mg/5 mL, 187 mg/5 mL, and 250 mg/5 mL	Do.
NDA 050775	Biaxin XL Filmtab (clarithromycin) Extended-release Tablets, 500 mg	Do.
NDA 209305	Eskata (hydrogen peroxide) Topical Solution, 40%	Aclaris Therapeutics, Inc., 640 Lee Rd., Suite 200, Wayne, PA 19087
NDA 211210	Qmiiz ODT (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg	TerSera Therapeutics LLC, 520 Lake Cook Rd., Suite 500, Deerfield, IL 60015

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** 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: August 10, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*