By direction of the Commission.

Joel Christie,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2422]

Teva Branded Pharmaceutical Products R&D, Inc., et al.; Withdrawal of Approval of 39 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 39 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 3, 2025.

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 table 1 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.

TABLE1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 012674	Hexadrol (dexamethasone), Elixir, 0.5 mg/5 milliliter (mL)	Aspen Global Inc., c/o Lachman Consultant Services, Inc., 1600 Stewart Ave., Westbury, NY 11590.
NDA 012675	Hexadrol (dexamethasone) Tablets, 0.5 mg, 0.75 mg, 1.5 mg, and 4 mg.	Do.
NDA 014694	Hexadrol (dexamethasone sodium phosphate) Injectable, Equivalent to (EQ) 4 mg phosphate/mL, EQ 10 mg phosphate/mL, and EQ 20 mg phosphate/mL.	Do.
NDA 016012	Vivactil (protriptyline hydrochloride (HCl)) Tablets, 5 mg and 10 mg ...	Teva Women's Health, Inc, 145 Brandywine Parkway, West Chester, PA 19380.
NDA 016792	Surmontil (trimipramine maleate) Capsules, EQ 25 mg base, EQ 50 mg base, and EQ 100 mg base.	Do.
NDA 016798	Sinequan (doxepin HCl) Capsules, EQ 10 mg base, EQ 25 mg base, EQ 50 mg base, EQ 75 mg base, EQ 100 mg base, and EQ 150 mg base.	Pfizer Inc, 66 Hudson Blvd. East, New York, NY 10001.
NDA 017516	Sinequan (doxepin HCl) Concentrate, EQ 10 mg base/mL	Do.
NDA 017525	Loxitane (loxapine succinate) Capsules, EQ 5 mg base, EQ 10 mg base, EQ 25 mg base, and EQ 50 mg base; Loxitane (loxapine succinate) Tablets, EQ 10 mg base, EQ 25 mg base, and EQ 50 mg base.	Teva Branded Pharmaceutical Products R&D, LLC, 145 Brandywine Parkway, West Chester, PA 19380.
NDA 017658	Loxitane C (loxapine HCl) Concentrate, EQ 25 mg base/mL	Do.
NDA 017693	Drytec Technetium Tc99m Generator (technetium Tc99m sodium pertechnetate generator) Solution, 830–16600 millicurie (mCi)/generator, and 68–2703 mCi/generator.	GE HealthCare, 251 Locke Dr., Marlborough, MA 01752.
NDA 018110	Thallous Chloride Tl-201 (thallous chloride Tl-201) Injectable, 1 mCi/mL.	Do.
NDA 018920	M.V.I. Pediatric (ascorbic acid 80mg/vial; biotin 0.02 mg/vial; cyanocobalamin 0.001mg/vial; dexpanthenol 5 mg/vial; ergocalciferol 0.01mg/vial; folic acid 0.14 mg/vial; niacinamide 17 mg/vial; phytonadione 0.2 mg/vial; pyridoxine HCl 1 mg/vial; riboflavin 5′-phosphate sodium 1.4 mg/vial; thiamine HCl EQ 1.2 mg base/vial; vitamin A 0.7 mg/vial; vitamin E 7 mg/vial) For Solution.	Hospira, Inc., a Pfizer company, 275 North Field Drive, Lake Forest, IL 60045.
NDA 019240	E–Z Scrub 201 (povidone-iodine) Sponge, 20%	Becton, Dickinson and Company, 75 N Fairway Dr., Vernon Hills, IL 60061.
NDA 019476	E–Z Scrub 241 (povidone-iodine) Sponge, 10%	Do.
NDA 020551	Nimbex (cisatracurium besylate) Injectable, EQ 2 mg base/mL; Nimbex Preservative Free (cisatracurium besylate) Injectable, EQ 2 mg base/mL and EQ 10 mg base/mL.	AbbVie Inc., N Waukegan Rd., North Chicago, IL 60064.
NDA 020655	Alora (estradiol) Extended-release Films, 0.025 mg/24 hour, 0.05 mg/24 hour, 0.075 mg/24 hour, and 0.1 mg/24 hour.	Do.
NDA 020933	Viramune (nevirapine), Suspension, 50 mg/5 mL	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., Ridgefield, CT 06877–0369.
NDA 021071	Avandia (rosiglitazone maleate) Tablets, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base.	Woodward Pharma Services, LLC, 11705 Boyette Rd., Riverview, FL 33569.
NDA 021290	Zinecard (dexrazoxane HCl) Injectable, EQ 250 mg base/vial and EQ 500 mg base/vial.	Pfizer Inc.
NDA 021591	Riomet (metformin HCl) Solution, 500 mg/5 mL	Ranbaxy Signature LLC c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.

TABLE1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
NDA 021610	Opana ER (oxymorphone HCl) Extended-release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Endo Operations Limited, c/o Endo USA, Inc., 9 Great Valley Parkway, Malvern, PA 19355.
NDA 021625	M.V.I. Adult (ascorbic acid 200 mg/vial; biotin 0.06 mg/vial; cyanocobalamin 0.005 mg/vial; dexpanthenol 15 mg/vial; ergocalciferol 0.005 mg/vial; folic acid 0.6 mg/vial; niacinamide 40 mg/vial; pyridoxine HCl 6 mg/vial; riboflavin 5′-phosphate sodium 3.6 mg/vial; thiamine HCl 6 mg/vial; Vitamin A 1 mg/vial; Vitamin E 10 mg/vial; Vitamin K 0.15 mg/vial) Injectable.	Hospira, Inc., a Pfizer company.
NDA 021773	Byetta (exenatide synthetic) Injectable, 300 micrograms (mcg)/1.2 mL and 600 mcg/2.4 mL.	AstraZeneca AB c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 022107	Tekturna HCT (aliskiren hemifumarate and hydrochlorothiazide) Tablets, EQ 150 mg base; 12.5 mg, EQ 150 mg base; 25 mg, EQ 300 mg base; 12.5 mg, and EQ 300 mg base; 25 mg.	Noden Pharma DAC c/o APCER Life Sciences, 111 Town Square Place, Suite 860, Jersey City, NJ 7310.
NDA 022200	Bydureon (exenatide synthetic) For Suspension, Extended-release, 2 mg/vial; Bydureon Pen (exenatide synthetic) For Suspension, Extended-release, 2 mg.	AstraZeneca AB c/o AstraZeneca Pharmaceuticals LP.
NDA 022450	Ofirmev (acetaminophen) Solution, 1000 mg/100 mL (10 mg/mL)	Mallinckrodt Pharmaceuticals Ireland Limited, Mallinckrodt Hospital Products Inc., 675 James S. McDonnell Blvd., Hazelwood, MO 63042.
NDA 022519	Duexis (famotidine and ibuprofen) Tablet, 26.6 mg; 800 mg	Horizon Medicines LLC, 1 Horizon Way, Deerfield, IL 60015.
NDA 050577	Zanosar (streptozocin) Injectable, 1 gram(g)/vial	Teva Pharmaceuticals USA, Inc., 145 Brandywine Parkway, West Chester, PA 19380.
NDA 050693	Zithromax (azithromycin), for Suspension, EQ 1 g base/packet	Pfizer Inc.
NDA 050591	Bactroban (mupirocin) Ointment, 2%	SmithKlineBeecham (Cork) Ltd., Ireland c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 050703	Bactroban (mupirocin) Nasal Ointment, 2%	Do.
NDA 050746	Bactroban (mupirocin) Cream, 2%	Do.
NDA 050797	Zmax (azithromycin) for Suspension, Extended-release, EQ 2 g base/bottle.	PF Prism C.V. c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 207986	Otiprio (ciprofloxacin) Injectable and Otic Suspension, 6% (60 mg/mL).	ALK-Abelló, Inc. c/o ALK Inc., 135 Route 202/206 Suite 3, Bedminster, NJ 07921.
NDA 208653	Apadaz (acetaminophen and benzhydrocodone HCl), Tablets, 325 mg; EQ 4.08 mg base, 325 mg; EQ 6.12 mg base, and 325 mg; EQ 8.16 mg base.	Zevra Therapeutics, 1180 Celebration Blvd., Suite 103, Celebration, FL 34747.
NDA 209210	Bydrueon BCise (exenatide synthetic) Extended-release Suspension, 2 mg/0.85 mL.	AstraZeneca AB c/o AstraZeneca Pharmaceuticals LP.
NDA 209410	Osmolex ER (amantadine HCl) Extended-release Tablets, EQ 129 mg base, EQ 161 mg base, EQ 193 mg base, and EQ 258 mg base.	Supernus Pharmaceuticals, Inc., 9715 Key West Ave., Rockville, MD 20850.
NDA 212895	Conjupri (levamlodipine maleate) Tablets, EQ 1.25 mg base, EQ 2.5 mg base, and EQ 5 mg base.	CSPC Ouyi Pharmaceutical Co., Ltd. c/o CSPC Conjupro Biotherapeutics, Inc., 302 Carnegie Center, Suite 100, Princeton, NJ 08540.
NDA 214835	Risvan (risperidone) for Suspension, Extended-release, 75 mg and 100 mg.	Laboratorios Farmacéuticos ROVI, S.A. c/o PharmaLex US Corporation, 1 West 1st Ave., Conshohocken, PA 19428.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of September 3, 2025. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on September 3, 2025 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: July 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–0410]

Determination That ROXICET (Oxycodone Hydrochloride and Acetaminophen) Tablet, 5 Milligrams and 325 Milligrams, Was 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 ROXICET (oxycodone