TABLE1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued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.

[FR Doc. 2025–14683 Filed 8–1–25; 8:45 am]

BILLING CODE 4164–01–P

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

hydrochloride (HCl) and acetaminophen) tablet, 5 milligrams (mg)/325 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for oxycodone HCl and acetaminophen tablet, 5 mg/325 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Alexander Poonai, J.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *alexander.poonai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, is the subject of ANDA 087003, held by Hikma Pharmaceuticals USA Inc., and initially approved on February 25, 1980. ROXICET is indicated for the relief of moderate to moderately severe pain.

ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Nostrum Laboratories, Inc. submitted a citizen petition dated February 5, 2025 (Docket No. FDA–2025–P–0410), under 21 CFR 10.30, requesting that the Agency determine whether ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ROXICET (oxycodone HCl and acetaminophen) tablet, 5 mg/325 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 29, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14707 Filed 8–1–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–0477]

Determination That HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (Heparin Sodium) Injectable, 200 Units/100 Milliliters, and Two Other Drug Products Were 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 HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) injectable, 200 units/100 milliliters (mL); HEPARIN SODIUM 2,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) injectable, 200 units/100 mL; and HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) injectable, 1,000 units/100 mL under new drug application (NDA) 019042 were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these products if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Madeleine Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 240–863–8976, *madeleine.giaquinto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions