hydrochloride (HCl) and acetaminophen) tablet, 5 milligrams (mg)/325 mg, was not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161).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

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 an 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 (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) injectable, 200 units/100 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, are the subject of NDA 019042, held by B. Braun Medical Inc., and initially approved on March 29, 1985. These drug products are indicated as an anticoagulant to maintain catheter patency.

The HEPARIN SODIUM IN SODIUM CHLORIDE IN PLASTIC CONTAINER (heparin sodium) products listed in this document are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of March 4, 2005 (70 FR 10651), FDA announced that it was withdrawing approval of NDA 091042, effective April 4, 2005.

B. Braun Medical Inc. submitted a citizen petition dated February 17, 2025 (Docket No. FDA–2025–P–0477), under 21 CFR 10.30, requesting that the Agency determine whether the following drug products were withdrawn from sale for reasons of safety or effectiveness:

- HEPARIN SODIUM 1,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) injectable, 200 units/100 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.

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 the HEPARIN SODIUM IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) products listed in this document were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal from sale of the HEPARIN SODIUM IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) products listed in this document. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list the HEPARIN SODIUM IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (heparin sodium) products listed in this document 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 these drug products 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

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–N–1090]

Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Final Report; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice of availability entitled ''Prescription Drug User Fee Act VII; Independent Assessment of Communication Through Product Quality Information Requests During Application Review; Final Report; Availability; Request for Comments'' that appeared in the **Federal Register** of May 9, 2025. In the notice of availability, FDA requested comments on the final assessment report. The Agency is taking this action in response to a request to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the final report published May 9, 2025 (90 FR 19722). Either electronic or written comments must be submitted by September 3, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,