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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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No. FDA–2025–P–0477), under 21 CFR 10.30, requesting that the Agency determine whether the following drug products were withdrawn from sale for reasons of safety or effectiveness: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.

[FR Doc. 2025–14690 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–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,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–1090 for ''Independent Assessment of Communication Through Product Quality Information Requests During Application Review.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Mahesh Ramanadham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3272, email: *Mahesh.Ramanadham@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 9, 2025, FDA published a notice of availability with a 30-day comment period to request comments on the document entitled ''Product Quality Information Request Communications Assessment: Final Report.'' FDA requested feedback on: (1) the assessment findings and recommendations, (2) whether certain recommendations are more desirable than others, and (3) other actions FDA and applicants should consider and why.

The Agency has received a request for a 30-day extension of the comment period for the notice of availability. The request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a thoughtful, substantive response to the notice of availability.

FDA has considered the request and is reopening the comment period for the notice of availability for 30 days, until September 3, 2025. The Agency believes that the additional 30-days allow adequate time for interested persons to submit comments.

Dated: July 30, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14684 Filed 8–1–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5964]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on January 15, 2025.

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, 301–796–3471, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of February 14, 2025. The document erroneously included four previously withdrawn ANDAs; ANDA 079075 for Fentanyl Citrate (fentanyl citrate) tablet, Equivalent to (EQ) 0.1 milligrams (mg) base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base, held by Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Bldg. A, Parsippany, NJ 07054; ANDA 206155 for Olanzapine (olanzapine) tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, held by RegCon Solutions, LLC, U.S. Agent for Indoco Remedies Ltd., 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121; ANDA 206204 for Piperacillin and Tazobactam (piperacillin and tazobactam) injectable, EQ 12 grams (g) base/vial and EQ 1.5 g base/vial, held by Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047; and ANDA 209708 for Mivacurium Chloride (mivacurium chloride) solution, EQ 10 mg base/5 milliliters (mL) (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL), held by Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393. This notice corrects that error. Because ANDAs 079075, 206155, 206204, and 209708 were withdrawn previously in the September 19, 2024 **Federal Register** notice titled ''Allergan, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug