

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](mailto: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]

**BILLING CODE 4164-01-P**

## 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](mailto: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

Applications,” those ANDA withdrawals still have an effective date of October 21, 2024.

### Correction

In the **Federal Register** of Wednesday, January 15, 2025 (90 FR 3876), appearing on page 3876, 3877 in FR Doc. 2025–00742, the following correction is made:

On page 3876–3877, in the table, the entries for ANDAs 079075, 206155, 206204, and 209708 are removed.

Dated: July 30, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–14682 Filed 8–1–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review; Group Cellular and Molecular Biology of Glia Study Section.

*Date:* October 16–17, 2025.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Sung-Wook Jang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 812P, Bethesda, MD 20892, (301) 435–1042, [jangs2@csr.nih.gov](mailto:jangs2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: High-Priority Research in Tobacco Regulatory Science.

*Date:* October 16–17, 2025.

*Time:* 9:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–9295, [mooremar@mail.nih.gov](mailto:mooremar@mail.nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group; Maximizing Investigators' Research Award—D Study Section.

*Date:* October 16–17, 2025.

*Time:* 10:00 a.m. to 6:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Anne Marie Strohecker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (202) 924–4186, [stroheckeram@csr.nih.gov](mailto:stroheckeram@csr.nih.gov).

*Name of Committee:* Risk, Prevention and Health Behavior Integrated Review Group; Lifestyle Change and Behavioral Health Study Section.

*Date:* October 16–17, 2025.

*Time:* 10:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Pamela Jeter, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 10J08, Bethesda, MD 20892, (301) 827–6401, [pamela.jeter@nih.gov](mailto:pamela.jeter@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 30, 2025.

**Bruce A. George,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025–14677 Filed 8–1–25; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Institute of Mental Health.

*Date:* September 16–18, 2025.

*Time:* September 16, 2025, 1:30 p.m. to 4:55 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Address:* Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892, In Person and Virtual Meeting.

*Time:* September 17, 2025, 10:30 a.m. to 6:25 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Address:* Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892, In Person and Virtual Meeting.

*Time:* September 18, 2025, 9:45 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Address:* Porter Neuroscience Research Center, Building 35A, 35 Convent Drive, Bethesda, MD 20892, In Person and Virtual Meeting.

*Contact Person:* Jennifer E. Mehren, Ph.D., Scientific Advisor, Division of Intramural Research Programs, National Institute of Mental Health, National Institutes of Health, 35A Convent Drive, Bethesda, MD 20892–3747, 301–496–3501, [mehrenj@mail.nih.gov](mailto:mehrenj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: July 30, 2025.

**Bruce A. George,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025–14676 Filed 8–1–25; 8:45 am]

**BILLING CODE 4140–01–P**