

submission of ICSRs and ICSR attachments to AEMS: (1) direct submission through the ESG NextGen, or (2) submission through the Safety Reporting Portal (SRP). The SRP enables submission of ICSRs and ICSR attachments by applicants, specified nonapplicants, and responsible persons for companies with reporting requirements who do not have ICH E2B(R3) data standards capability. This notice regarding the use of ICH E2B(R3) data standards applies only to submission of ICSRs and ICSR attachments through the ESG NextGen. The eSRR Guidance incorporates by reference the technical specifications described in the ICH E2B(R3) FDA Regional Implementation Guidance, which addresses topics such as data elements, electronic transport format, and types of ICSR attachments and is periodically updated. To ensure that you have the most recent version of the technical specifications document and for additional information on electronic submissions to AEMS, check the FDA Adverse Event Monitoring System (AEMS) Electronic Submissions web page at <https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-electronic-submissions>.

The technical specifications document entitled “Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments” (available at <https://www.fda.gov/media/132096/download>) discusses how ICSRs and ICSR attachments should be electronically prepared in accordance with the ICH E2B(R2) data standards, which are the data standards that FDA will continue to accept through September 30, 2026.

In January 2024, FDA began accepting electronic submissions of postmarketing ICSRs for human drug products, biological products, and drug- or biologic-led combination products submitted to AEMS in electronic format using the ICH E2B(R3) data standards and announced that submitters could continue to submit using E2B(R2) standards for an additional two years during the E2B(R3) implementation period. To facilitate implementation and enhance efficiency and alignment with internationally harmonized data standards, FDA is requiring that ICSRs submitted through ESG NextGen must be in the ICH E2B(R3) data standards beginning on October 1, 2026, unless earlier transition to ICH E2B(R3) data standards is needed to accommodate reporting requirements (see, for example, 21 CFR 314.81(b)(3)(v), added by the final rule entitled “Nonprescription Drug Product With an

Additional Condition for Nonprescription Use” (89 FR 105288, December 26, 2024)).

We intend to no longer accept postmarketing ICSRs using ICH E2B(R2) data standards for human drug products, biological products, and drug- or biologic-led combination products after September 30, 2026. Once an applicant, specified nonapplicant, or responsible person for a company with reporting requirements has begun submitting ICSRs in the ICH E2B(R3) data standards format, all ICSR submissions are expected to use this data standard. For general questions or assistance, see **FOR FURTHER INFORMATION CONTACT** or contact aemsesub@fda.hhs.gov.

(Authority: 21 CFR 4.102, 230.220(c)(1), 310.305(e)(1), 314.80(g)(1), 314.81(b)(3)(v)(F)(1), 314.98, 329.100(c)(1), and 600.80(h)(1))

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–06660 Filed 4–3–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–P–6868]

Determination That STRATTERA (Atomoxetine Hydrochloride) Capsules 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams, 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 STRATTERA (atomoxetine hydrochloride) capsules 5 milligrams, 10 milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Rana Carroll, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6218, Silver Spring, MD 20993–0002, 301–796–6135, Rana.Carroll@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 (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

STRATTERA (Atomoxetine Hydrochloride) Capsules 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams, is the subject of NDA 021411, held by Eli Lilly and Co, and initially approved on November 26, 2022. STRATTERA is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

In a letter dated August 5, 2025, Eli Lilly and Company notified FDA that STRATTERA (Atomoxetine

Hydrochloride) Capsules 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligram, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Rosemont Pharmaceuticals Holdings, Inc submitted a citizen petition dated December 4, 2025 (Docket No. FDA–2025–P–6868), under 21 CFR 10.30, requesting that the Agency determine whether STRATTERA (Atomoxetine Hydrochloride) 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams capsules were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 Milligrams strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

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 STRATTERA (Atomoxetine Hydrochloride) 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams capsules, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that STRATTERA (Atomoxetine Hydrochloride) 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams capsules were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of STRATTERA (Atomoxetine Hydrochloride) 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80 Milligrams, and 100 Milligrams capsules, 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 STRATTERA (Atomoxetine Hydrochloride) 5 Milligrams, 10 Milligrams, 18 Milligrams, 25 Milligrams, 40 Milligrams, 60 Milligrams, 80

Milligrams, and 100 Milligrams capsules, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–06661 Filed 4–3–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Hazardous Waste Worker Training—42 CFR Part 65, National Institute of Environmental Health Sciences (NIEHS)

Correction

In notice document 2026–05238 appearing on pages 13043–13044 in the issue of Wednesday, March 18, 2026, make the following correction:

On page 13043, in the third column, in the **DATES** section, “March 18, 2026” should read “April 17, 2026”.

[FR Doc. C1–2026–05238 Filed 4–3–26; 8:45 am]

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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: Center for Scientific Review Special Emphasis Panel; Special: Integrative Myocardial Physiology.

Date: April 28, 2026.

Time: 9:30 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: Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4136, Bethesda, MD 20892, 301–435–0904, sara.ahlgren@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Ruth L. Kirschstein National Research Service Award.

Date: April 29–30, 2026.

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

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 204–0329, tandlea@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Understanding Mechanistic Impacts of Micro- and Nanoplastics in Organ/Tissue Dysfunction.

Date: April 29, 2026.

Time: 10:00 a.m. to 2:30 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: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/ Room 3171, Research Triangle Park, NC 27709, (984) 287–3340, worth@niehs.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Auditory, Sensory-Motor, Language, Communication and Related Neuroscience.

Date: April 29, 2026.

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: Kausik Ray, Ph.D., Scientific Review Officer, Center for