

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2026-P-1636]

Determination That TOVALT ODT (Zolpidem Tartrate) Orally Disintegrating Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.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, Agency, or we) has determined that TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for zolpidem tartrate, orally disintegrating tablets, 5 mg and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993-0002, 240-402-9674, sungjoon.chi@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effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 mg, are the subject of NDA 021412, held by Biovail Laboratories International SRL, and initially approved on April 25, 2007. TOVALT ODT is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

In a letter dated January 8, 2015, Valeant Pharmaceuticals North America, LLC, requested withdrawal of approval of NDA 021412 for TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 mg. In the **Federal Register** of June 21, 2017 (82 FR 28322), FDA announced that it was withdrawing approval of NDA 021412, effective July 21, 2017.

LGM Pharma Solutions, LLC, submitted a citizen petition dated February 12, 2026 (Docket No. FDA-2026-P-1636), under 21 CFR 10.30, requesting that the Agency determine whether TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 mg, were 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 TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 mg, were withdrawn from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug

product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TOVALT ODT (zolpidem tartrate) orally disintegrating tablets, 5 mg and 10 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 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 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. 2026-13820 Filed 7-8-26; 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: Center for Scientific Review Special Emphasis Panel; Bioengineering and Instrumentation Development Review Panel.

Date: July 29, 2026.

Time: 9:00 a.m. to 3:00 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: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD