



Food and Drug Administration

[Docket No. FDA-2024-N-5933]

Notice of Decision on a Hearing Request Regarding a Proposal to Refuse to Approve a New Drug Application for TRADIPITANT Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its decision on a request for a hearing regarding the proposal of FDA’s Center for Drug Evaluation and Research (CDER) to refuse to approve a new drug application (NDA) 218489, submitted by Vanda Pharmaceuticals, Inc. (Vanda), for TRADIPITANT capsules (85 mg) with the proposed indication for “the treatment of [symptoms of] or [nausea in] in gastroparesis” (“symptoms of gastroparesis”). The decision is available in the docket identified by the number in brackets in the heading of this document.

DATES: The decision was submitted to the docket on March 26, 2026.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, Maryland 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

On September 18, 2023, Vanda submitted NDA 218489 for TRADIPITANT capsules, 85 milligrams (mg), pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) with the proposed indication for “the treatment of [symptoms of] or [nausea in] in gastroparesis” (“symptoms of gastroparesis”). TRADIPITANT is a selective neurokinin-1 (NK-1) receptor antagonist.

On September 18, 2024, the Office of Immunology and Inflammation (OII) in CDER issued a complete response letter (CRL) to Vanda under 21 CFR 314.110, stating that NDA 218489 could not be approved in its present form. The CRL described specific deficiencies and, where possible, recommended ways that Vanda might remedy those deficiencies. On November 25, 2024, Vanda indicated that it wished to receive approval of its application or a notice of opportunity for a hearing (NOOH). On January 7, 2025, CDER sent Vanda a NOOH and proposal to refuse approval of TRADIPITANT to treat gastroparesis, which was then published in the *Federal Register* on January 16, 2025 (90 FR 4748).

On January 28, 2025, Vanda provided a notice of participation and request for a hearing. On March 17, 2025, Vanda submitted documentation and analysis in support of a request for summary judgment, or alternatively, a hearing. On July 18, 2025, CDER submitted a Proposed Order denying Vanda's request for a hearing, and on September 17, 2025, Vanda submitted its reply to CDER's Proposed Order.

After considering the parties' submissions, on March 26, 2026, FDA issued a decision regarding Vanda's request for a hearing on CDER's proposal to refuse to approve NDA 218489.

II. Docket Access

For access to the docket to read the final decision and other documents pertaining to this matter, 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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