NDA 022192/S-023

GENERAL ADVICE

Vanda Pharmaceuticals, Inc.
Attention: Gunther Birznieks
Research & Development Committee Member
2200 Pennsylvania Ave NW, Suite 300E
Washington, DC 20037

Dear Gunther Birznieks:[1]

Please refer to your supplemental new drug application (sNDA) dated June 2, 2023, received June 2, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fanapt (iloperidone) tablets.

We also refer to the April 2, 2024, approval letter for your June 2, 2023, supplement which provided for the addition of the following indication: acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

We note that the incorrect PMR numbers were listed in the April 2, 2024, approval letter. The correct PMR numbers are as follows:

4606-1 Conduct a GLP juvenile animal study to assess the toxicology of iloperidone in juvenile rats to support clinical trials of iloperidone in the intended pediatric population ages 10 to <13 years.

Final Protocol Submission: 04/2024
Study Completion: 04/2025
Final Report Submission: 10/2025

4606-2 Conduct an open-label, multiple oral dose study to demonstrate the safety, tolerability, and pharmacokinetics of iloperidone in patients ages 10 to <13 years with manic or mixed episode associated with bipolar I disorder.

Draft Protocol Submission: 03/2025
Final Protocol Submission: 07/2025
Study Completion: 07/2026
Final Report Submission: 01/2027

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

4606-3 Conduct an open-label study to assess the long-term safety of iloperidone in patients aged 10 to <13 years with bipolar I disorder.

Draft Protocol Submission: 03/2025
Final Protocol Submission: 07/2025
Study Completion: 07/2030
Final Report Submission: 01/2031

Please disregard the PMR numbers listed in the April 2, 2024, approval letter.

If you have any questions, contact Tiffanie Taylor, Regulatory Project Manager, at Tiffanie.Taylor@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tiffany R. Farchione, MD
Director
Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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