Court Orders FDA to Resolve Vanda Pharmaceuticals' Jet Lag Hearing Request by March 5, 2024

January 30, 2024

WASHINGTON, Jan. 30, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the United States District Court for the District of Columbia granted Vanda's motion for summary judgment on its claim against the United States Food and Drug Administration (FDA) for unlawfully delaying a hearing on the approvability of Vanda's supplemental new drug application (sNDA) for HETLIOZ® to treat jet lag disorder (*Vanda Pharmaceuticals Inc. v. FDA*, case no. 1:22-cv-2275-CJN).

The Federal Food, Drug, and Cosmetic Act (FDCA) requires the FDA to either approve a new drug application or provide an opportunity for a hearing within 180 days after submission of the application.[1] Vanda submitted its sNDA in October 2018 for approval to market HETLIOZ® to treat jet lag disorder. The FDA did not comply with the statute and did not timely approve or provide an opportunity for a hearing. Instead, the FDA issued a complete response letter in August 2019.

Following multiple attempts to informally resolve the complete response letter, Vanda requested an opportunity for a hearing in July 2022, and the FDA provided Vanda a private notice of an opportunity for a hearing. After doing so, the FDA was required under the FDCA to commence the hearing within 120 days[2], but the FDA failed to meet this legal obligation.

To remedy the FDA's extraordinary delays, Vanda filed its lawsuit in September 2022. On January 26, 2024, a federal judge ruled that the FDA "has violated the statute" and ordered the FDA to either finally resolve Vanda's sNDA or commence a hearing on the sNDA on or before March 5, 2024. As the Court explained, "the statute requires that a hearing shall commence within 300 days after an application is filed. Vanda's application has been pending for almost 2,000 days and it has been over 500 days since Vanda made its most recent request for hearing."

The Court's decision highlights the serious flaws in FDA regulations governing drug-approval processes, and it reinforces the FDA's clear statutory obligations to render timely final decisions on drug applications. It appears from this case, and from the FDA's standard policies, that FDA decisionmakers have implemented a policy of following the FDA's own timelines, resulting in unlawful actions that are systemic. The FDA's extraordinary delays impede medical innovation to the detriment of the many patients with unmet needs who lack effective therapeutics. The FDA's delays force these patients to wait years longer than Congress envisioned for access to urgently needed pharmaceutical innovation.

References

1. 21 U.S.C. § 355(c)(1)
2. 21 U.S.C. § 355(c)(1)(B)

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

About HETLIOZ®

For full U.S. Prescribing Information for HETLIOZ®, including indication and Important Safety Information, visit www.hetlioz.com.

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