Vanda Pharmaceuticals Calls on FDA to Withdraw Proposal from FY 2027 Legislative Agenda That Would Extend Drug Review Timelines

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WASHINGTON, April 9, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today highlighted a legislative proposal contained in the FDA's FY 2027 Congressional Budget Justification.

The proposal would eliminate the simple statutory requirement that the FDA must review a new drug application (NDA) within 180 days of filing.

In plain terms, this change would extend statutory review timelines rather than shorten them. It would replace the 180-day legal requirement with the longer Prescription Drug User Fee Act (PDUFA) and Generic Drug User Fee Amendments (GDUFA) performance goals. Under those goals, the FDA takes up to two months simply to decide whether to "file" the application. Only after that does the official review clock begin, resulting in typical total review times of 10 to 12 months from submission to decision.

The proposal would also replace the formal evidentiary hearing process required by current law with a weaker, internal streamlined appeal. The FDA has avoided providing the statutorily mandated opportunity for a formal evidentiary hearing on drug non-approvals for over 40 years, until Vanda's successful litigation forced the agency to grant the first such hearing in more than four decades.

"The FDA's current practice of exceeding the 180-day statutory timeline by issuing Complete Response Letters and operating under longer PDUFA timelines has already been ruled by federal courts to violate the law," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of the Board of Vanda Pharmaceuticals. "Instead of complying with the law as written, this proposal asks Congress to change the law so the slower system becomes legal. This is especially concerning because Commissioner Makary said just days ago that the current two-month filing review is too long and should take just days—yet this proposal seeks to codify that very delay into law. At the same time, the FDA seeks to replace the formal hearing process with a streamlined internal appeal, despite the U.S. Court of Appeals for the D.C. Circuit having ruled only months ago that the FDA unlawfully denied Vanda a proper hearing in the HETLIOZ® jet-lag case, and after the agency was compelled to grant Vanda the first formal drug approval hearing statutorily required but effectively avoided by the FDA for more than forty years."

Vanda supports genuine efforts to cut red tape and improve efficiency. However, this proposal does the opposite: it entrenches longer review times, reduces transparency for patients, and protects bureaucratic inertia instead of innovation. American patients would wait longer for needed medicines, while small innovators like Vanda would face greater financial risk and uncertainty.

Vanda calls on FDA Commissioner Dr. Marty Makary to withdraw this provision from the FY 2027 legislative agenda and urges Congress to reject the proposal.

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.

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