Vanda's Letter to FDA Commissioner Highlights Faulty Gastroparesis NDA Review

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WASHINGTON, Jan. 8, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) letter to FDA Commissioner highlights faulty gastroparesis NDA review.

As previously reported, Vanda has sought approval from the U.S. Food and Drug Administration (FDA) for tradipitant for the treatment of patients with gastroparesis. FDA declined to approve Vanda's New Drug Application (NDA) for tradipitant for the treatment of symptoms of gastroparesis, providing Vanda with a Complete Response Letter (CRL) on September 18, 2024.

Today, Vanda issued a letter to FDA Commissioner Robert M. Califf, MD, regarding the September 18, 2024 CRL in reference to Vanda's NDA for tradipitant for the treatment of gastroparesis. The full letter is shown below:

Dear Dr. Califf:

We are writing to bring your attention to a disturbing pattern of conduct at FDA that impairs the credibility of the agency and harms the American public. In an interview last year you stated that you would not overrule decisions made by civil servants at the Agency except in certain cases of "corruption" or "temporary insanity" of the decision maker.[1] Neither the public nor regulated entities like Vanda are able to determine what instances of "corruption" or "temporary insanity" would in your view merit overruling lower-level FDA employee decisions. This opacity in decisionmaking and oversight has allowed a culture of obfuscation and closemindedness to fester at FDA. And your agency's review of our application to market tradipitant is no exception.

Three months ago, Vanda received a complete response letter (CRL), dated September 18, 2024, in response to the new drug application (NDA) Vanda submitted on September 18, 2023, for the use of tradipitant for the treatment of symptoms of gastroparesis, a serious and debilitating gastrointestinal disorder. We wrote to Dr. Nikolov expressing our surprise "by the sheer disregard for the facts, evidence, and basic scientific principles contained in the complete response"—a letter that could not "possibly reflect a legitimate regulatory review" as it did not "provide reasoned explanations or engage with the evidence we presented on its merit—including voluminous evidence from experts."

Three months later, Dr. Nikolov has not even acknowledged that letter, let alone provided a response. This is unacceptable, and stems from the seriously misguided nature of your position that you will not overrule decisions made by civil servants at the Agency except in extreme situations such as "corruption" or "temporary insanity" of the decision maker. As a political appointee and head of the agency, you are the only person accountable to the American public—a public that needs to know that the agency will follow the law and ensure courteous and civil behavior by agency employees.

In addition, FDA has denied our request to convene an Advisory Committee to consider our application for tradipitant, a process by which experts and the public can voice their opinion on our application. As you are no doubt aware, the number of Advisory Committee meetings convened by the agency has drastically declined over the last few years. *See* Cheri Banks, *The Future of Voting for FDA Advisory Committees*, Federation of American Scientists (Sept. 9, 2024), perma.cc/L8R3-2FJD (noting that in 2021, 6% of drug applications were referred to advisory committees, down from 55% in 2010). You have stated separately that there should be "less voting" by advisory committees, and that you don't believe in "gladiator votes" because "votes don't matter." These statements compound a sentiment that the agency avoids public scrutiny of its decisions, which is dangerous both for public health and agency credibility.

I understand that you may be leaving the agency in the new administration, but I hope that you will consider this letter, and I would welcome your thoughts in response. FDA's policies, practices, and culture must be evaluated and corrected so as to align with scientific evidence and the law.

Sincerely,

Mihael H. Polymeropoulos, M.D.
Chief Executive Officer
Vanda Pharmaceuticals Inc.

1. MedPage Today, P*olitics and Controversy in the FDA*, YouTube (Apr. 11, 2023) (statement of Commissioner Robert Califf, M.D.), *available at* https://www.youtube.com/watch?reload=9&app=desktop&v=zGrnzM51Jrs.

The text of the letter to Dr. Nikolov, referenced in the second paragraph of the letter above, is available at: https://assets.vandapharma.com/pdfs/vanda-letter-to-dr-nikolov.pdf

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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