Vanda Ruling Opens Door For Contesting FDA Drug Denials

By **Chad Landmon, Claire Davies and Suzanne Bassett** (September 24, 2025)

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Since the U.S. Supreme Court's Loper Bright **decision** last year, one question that is often asked is whether companies will more aggressively challenge U.S. Food and Drug Administration product approval denials in court.

In what may be an affirmative answer to that question and a harbinger of things to come, on Aug. 15 the U.S. Court of Appeals for the D.C. Circuit sided with Vanda Pharmaceuticals in its ongoing fight to obtain FDA approval of its Hetlioz (tasimelteon) product for jet lag, reversing the FDA's refusal to hold a hearing to resolve potential factual disputes relating to Vanda's clinical trials.[1]

The court remanded the case, Vanda Pharmaceuticals Inc. v. FDA, to the FDA for further proceedings, emphasizing that Vanda's evidence raised genuine factual disputes that warranted a hearing.

What This Precedent Means for Drug Companies

Although the FDA may potentially reaffirm its nonapproval decision, the D.C. Circuit certainly opened the door for more legal challenges to FDA nonapproval decisions in the future, and set a clear precedent requiring the FDA to meaningfully engage with evidence presented by sponsors in hearing requests.

At the very least, we are likely to see an increase in the number of hearings held by the FDA, creating new opportunities for drug companies to advocate for their product approvals.

Background

In 2018, Vanda applied to the FDA for approval to market tasimelteon — a drug previously approved as a treatment for a rare sleep disorder — as a treatment for jet lag.

In 2019, the FDA issued a complete response letter, or CRL, indicating that the agency could not approve the drug application in its present form. The FDA and at least one court have taken the position that such CRLs are not final agency action, so courts lack jurisdiction to review challenges to them.

Instead, after receiving a CRL, sponsors can choose to resolve the cited deficiencies and resubmit the application, withdraw the application or request a hearing on the CRL, pursuant to Title 21 of the Code of Federal Regulations, Section 314.110(b).

Vanda submitted two formal dispute resolution requests after receiving the CRL, arguing that tasimelteon should be approved for jet lag. Alternatively, Vanda contended that even with the FDA's critiques, there was sufficient evidence to approve tasimelteon for treating insomnia symptoms related to jet lag.

However, FDA officials denied both requests, upholding the initial determination that Vanda had failed to provide substantial evidence of effectiveness to support the original indication — the proposed use for treating jet lag — and declining to consider the narrower one, insomnia symptoms related to jet lag, because Vanda proposed it only after receiving the CRL.

Vanda argued that the FDA was required by statute to hold a hearing before denying the application under the Federal Food, Drug and Cosmetic Act, and further noted that a hearing was required to resolve factual disputes over the adequacy of the clinical evidence it had submitted to support its application.

Vanda supplied five expert declarations responding to each of the FDA's objections and explaining, in the experts' views, that the three clinical trials that Vanda supplied as part of its application constituted substantial evidence of tasimelteon's efficacy for treating jet lag.

The FDA disagreed. Invoking its summary judgment procedures under Section 314.200(g)(1), the agency issued a final decision denying Vanda's application and its hearing request on the basis that there was "no genuine and substantial issue of fact justifying a hearing."

Legal Challenge and Holding

Vanda petitioned the D.C. Circuit to review the FDA's final decision and hearing denial under Section 355(h), which allows applicants to appeal an order refusing or withdrawing approval of a drug application. This appeal must be filed "in the D.C. Circuit or the applicant's circuit within 60 days of the order.

Vanda challenged the FDA's denial on three grounds, asserting that:

- The FDA unlawfully denied its request for hearing — either because the FDCA requires the FDA to conduct a hearing when an applicant requests one, or because Vanda raised a material issue of factual dispute precluding the FDA from issuing summary judgment;

- The FDA acted arbitrarily and capriciously by refusing to grant Vanda a narrower indication, and by demanding that Vanda offer evidence that its drug improved a second symptom of jet lag; and

- The principal deputy commissioner's issuance of the FDA's final decision violated the appointments clause.

The court sided with the FDA on the latter two points, finding no arbitrary or capricious action in refusing the narrower indication and ruling that Vanda forfeited the appointments clause challenge by not raising it earlier.

In response to the first argument, the D.C. Circuit disagreed with Vanda's claim that Sections 355(c) and 355(d) require the FDA to hold a hearing upon request. Instead, the

court determined that the statute allows for summary judgment when no material facts are in dispute. Crucially, however, the court agreed that, while the FDCA does not always require a hearing, Vanda was entitled to one in this case.

In siding with Vanda, the court rejected the FDA's claim that the evidence was conclusively deficient and that no material factual dispute existed. The court highlighted Vanda's expert testimonies and clinical studies, noting that the experts' views were specific, reasoned and rooted in evidence, unlike the FDA's general and unsupported assertions of insufficiency.

The court indicated that, if the FDA had identified a conclusive flaw in the experts' rationale or studies, the court might have considered the FDA's determination as reasonable and reasonably explained.

The court concluded that "even affording substantial deference to FDA's expertise, we cannot say on this record that FDA has reasonably articulated any conclusive flaw in Vanda's evidence that forecloses approval without requiring resolution of material factual disputes."

Therefore, the FDA could not properly deny Vanda's application without holding a hearing.

Key Takeaways for Drug Companies and Sponsors

The D.C. Circuit's ruling in favor of Vanda creates new opportunities and considerations for drug companies navigating the FDA approval process. Here's what sponsors should understand about this precedent-setting decision.

The FDCA does not create an automatic right to a hearing.

Relying on precedent interpreting a related provision of the FDCA, the court held that the FDCA does not create an automatic right to a hearing before the FDA denies a new drug application, and preserves the FDA's use of summary judgment when no issues of material facts are in dispute.

The court will defer to the FDA in some circumstances.

The court specified that it is more willing to defer to the FDA's decision-making where the agency identifies a "precise regulatory standard that forms the basis of its denial."

However, when the agency's denial is premised on a more general standard, such as the statutory "substantial evidence of effectiveness" standard at issue here, the court will scrutinize the record more closely.

This could become a crucial aspect of the opinion for sponsors aiming to contest nonapproval decisions in the future, as the level of evidence required to satisfy the substantial-evidence standard for a new drug application is often the subject of disagreement between the FDA and sponsors.

Requests for reconsideration and hearings should contain detailed scientific information.

In light of the ruling, the FDA may be more reticent to deny hearing requests that present well-crafted arguments disputing the scientific and factual bases of deficiencies cited in the underlying CRL. Sponsors should engage with experts and key opinion leaders when developing such requests.

Litigation is an option.

The D.C. Circuit's decision makes it clear that drug companies facing difficulty with approval pathways should consider litigation as an option, particularly when the FDA refuses to hold a hearing.

But companies should at all stages be mindful of creating the proper record before the agency: putting forth clinical data and expert testimony to support an approval tied to the FDA's requirements and, where applicable, its past decision-making on similar products.

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[1] Vanda Pharmaceuticals, Inc. v. FDA, Case No. 24-1049 (D.C. Cir. August 15, 2025).