FDA refuses to review Moderna’s mRNA flu vaccine

But in a letter dated February 3, Vinay Prasad, the FDA’s top vaccine regulator under the Trump administration, informed Moderna that the agency does not consider the trial “adequate and well-controlled” because the comparator vaccine “does not reflect the best-available standard of care.”

In its news release, Moderna noted that neither the FDA’s regulation nor its guidance to industry makes any reference to a requirement of the “best-available standard of care” in comparators.

“This decision by [the FDA’s Center for Biologics Evaluation and Research], which did not identify any safety or efficacy concerns with our product, does not further our shared goal of enhancing America’s leadership in developing innovative medicines,” Moderna CEO Stéphane Bancel said in the release. “It should not be controversial to conduct a comprehensive review of a flu vaccine submission that uses an FDA-approved vaccine as a comparator in a study that was discussed and agreed on with CBER prior to starting.”

Moderna said it has requested a meeting with the FDA to understand the basis of the refusal. “We look forward to engaging with CBER to understand the path forward as quickly as possible so that America’s seniors, and those with underlying conditions, continue to have access to American-made innovations.”

The company noted that mRNA-1010 has already been accepted for review in the European Union, Canada, and Australia.

https://arstechnica.com/health/2026/02/fda-refuses-to-review-modernas-mrna-flu-vaccine/