

Latest update on U.S. FDA BLA for Novavax's COVID-19 Vaccine

April 28, 2025

Last week, Novavax responded to the formal communication received from the U.S. Food and Drug Administration (FDA) for our Biologics License Application (BLA) and our response addresses the request for a postmarketing commitment (PMC) for a clinical trial. PMCs by their nature are completed after BLA approval. PMCs are not unusual with many approved drugs and/or biologics having at least one PMC or requirement. We believe our application is approvable upon alignment on the details of the PMC. We look forward to continued engagement with the FDA.