Asthma and Allergy Foundation of America

May 23, 2025

Division of Dockets Management
U.S. Food & Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments to the Docket for Public Comment on the Vaccines and Related Biological Products Advisory Committee [Docket No. 2025-N-1146]

On behalf of the Asthma and Allergy Foundation of America (AAFA), I am pleased to provide comments on the May 22, 2025, meeting of the Vaccines and Related Biological Products Advisory Committee (VRBAC). AAFA is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world.

AAFA supports vaccination efforts as an imperative front-line method of defense against COVID-19 and the many other respiratory diseases that threaten the life and safety of our community. Over 28 million people in the United States have asthma, including nearly 5 million children, and people with asthma are at higher risk for serious complications from certain vaccine-preventable diseases. Vaccines offer protection to those who receive them while also contributing to the health and immunity of the community. In addition, vaccination efforts should not be delayed in anticipation of a new method of vaccine development or composition which would impede accessibility to science-based standards of care.

It is imperative that COVID-19 vaccines remain accessible and available to all persons regardless of age or health risk. While vaccines are particularly crucial for persons living with certain chronic diseases like asthma and immunosuppressed groups, all people should have access to the vaccine to remain healthy and participate in generating community immunity. This includes ensuring continued vaccine access for all people, including those who are pregnant and play a critical role in protecting the health of their infants. As discussed at the most recent VRBAC meeting, infants and children less than 2 years of age remain immunologically naive and benefit from maternal vaccines and the vaccine series for protection.

The proposed FDA regulatory framework for COVID-19 vaccination also poses questions on timing and availability of the vaccine. As the vaccines are updated annually, the proposed regulation would impose a tremendous delay to the administration and availability of the vaccine. This could lead to delays in receiving the vaccine before the season begins, increasing the risk of transmission and possibly contributing to seasonal surges. The proposed framework also speaks to research ethics: when there is already an effective vaccine against COVID-19, placebo-controlled trials are not ethical. Delaying trials and gatekeeping treatments, especially when high-risk populations may be involved poses special ethical concerns and increases risk.

AAFA supports the VRBAC and encourages meetings to discuss not only the strain selection of COVID-19, but also the timing, availability, safety measures and communication of those measures to the public. VRBAC meetings provide the public with the opportunity to witness and consume the latest data and information on vaccines. We applaud the expert committee members and look forward to future VRBAC meetings that are regularly scheduled, open to the public, and available for public comment.

Thank you for the opportunity to comment.

Sincerely,

Kenneth Mendez

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America