November 18, 2020

Dear Mr. Siri and Ms. Brehm,

This is in response to your letter of October 7, 2020, regarding the composition of Data Safety Monitoring Boards overseeing clinical trials for COVID-19 vaccines. Thank you for sharing your comments.

FDA is a science-based regulatory agency and is focused on ensuring that vaccines that are approved or authorized for use are supported by the best available scientific and clinical evidence, and that the relevant statutory requirements for safety and effectiveness are met. In this regard, FDA is using all appropriate regulatory authorities and providing scientific and regulatory advice to expedite the development and availability of safe and effective therapeutics and vaccines to address COVID-19.

In general, a Data Monitoring Committee (DMC, also referred to as a Data Safety Monitoring Board or DSMB) is appointed by the study sponsor to evaluate the accumulating outcome data in one or more trials initiated by the particular sponsor. FDA's considerations regarding DSMB composition and operations are summarized in guidance (https://www.fda.gov/media/75398/download). The DSMB advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

We recognize that transparency around FDA's decision-making with respect to COVID-19 vaccines is likely to impact public confidence in these vaccines. We believe that the guidance documents issued in June (https://www.fda.gov/media/139638/download) and October (https://www.fda.gov/media/142749/download) 2020 provide insight into FDA's current thinking about the scientific data needed to support approval and authorization of COVID-19 vaccines. In addition to outlining our expectations for vaccine sponsors, we also hope both of these guidances help the public understand our science-based decision-making process that assures that any vaccine that is authorized or approved meets our high standards for safety and effectiveness. Please be assured that we are committed to principles of transparency, consistent with statutory authority and regulations.

Thank you again for sharing your comments.

Sincerely,

Peter Marks

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