June 18, 2021

Siri & Glimstad LLP
200 Park Avenue
New York, NY 10166

Dear Mr. Siri,

We have received the letter dated March 3, 2021 that you sent to FDA on behalf of Del Bigtree and the Informed Consent Action Network (ICAN), in which you reference FDA's December 11, 2020 response to ICAN's citizen petitions and petitions for administrative stay of action submitted to Docket Number FDA-2020-P-1601. Those petitions related to Phase 2 and Phase 3 clinical trials of vaccines to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

In the letter, you state that "ICAN finds FDA's response to this petition (and related documents) curious considering that 13 days after ICAN's initial petition was filed demanding placebo-controlled trials, the FDA released a guidance document on June 30, 2020 providing that these trials should include a placebo-controlled arm."

Since the start of the pandemic, FDA has been providing scientific and regulatory advice to companies, researchers, and others regarding the data needed to facilitate the manufacturing, clinical development, and approval of COVID-19 vaccines. FDA's June 2020 guidance document, *Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry* (available at https://www.fda.gov/media/139638/download) reflects this advice, including advice regarding the use of placebo controls.

In the letter, you also "request that the FDA confirm the placebo arm will be maintained through the conclusion of the trial in order to maintain the integrity of the trial and the validity of the safety data produced by the trial."

FDA agrees that it is important to continue to gather data about COVID-19 vaccines after they have been made available under EUA. FDA does not consider the availability of a COVID-19 vaccine under EUA, in and of itself, as grounds for immediately stopping blinded follow-up in an ongoing clinical trial of a COVID-19 vaccine or as grounds for offering an authorized COVID-19 vaccine to all placebo recipients in such a clinical trial.

As a general matter, as for all clinical trials, participants in a clinical trial of a COVID-19 vaccine may choose to discontinue participation at any time (see 21 CFR 50.25 (a)(8)).

Subjects enrolled in an ongoing trial of a COVID-19 vaccine who received placebo and who want to receive an authorized COVID-19 vaccine cannot be made to wait beyond the time that the vaccine would otherwise be available to them under the conditions of EUA, prioritization recommendations, and available supply.

As we noted in our guidance, FDA's expectation was that, following submission of an EUA request and issuance of an EUA, a sponsor would continue to collect placebo-controlled data in any ongoing trials for as long as feasible and would also work towards submission of a Biologics License Application (BLA) as soon as possible.

Thank you for your engagement on this topic.

Sincerely,

Lorrie H. Mcneill -S

Digitally signed by Lorrie H. Mcneill -S
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Date: 2021.06.18 11:25:22 -04'00'

Lorrie H. McNeill
Director
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research

cc: Dockets Management Staff