DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 10, 2020

Aaron Siri
Siri & Glimstad LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Sent via email to: aaron@sirillp.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA amend the study design for the Phase III trials of mRNA-1273 (NCT044070427), BNT162 (NCT04368728), AZD1222 (NCT04516746), and Ad26.COV2.S (NCT04505722)2 to provide that:

a. reduction in severe COVID-19 (i.e., hospital admissions, ICU admissions, and death) be a primary endpoint

b. PCR tests used to qualify an event of COVID-19 for a trials' endpoint use a maximum of 24 amplification cycles

c. interruption of transmission (person-to-person spread) be a primary endpoint; and

d. participants be tested for T-cell reactivity to SARS-CoV-2 pre-vaccination and post-vaccination

Your submission was received by this office on 11/09/2020. It was assigned docket number FDA-2020-P-2180. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,
Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.11.10 15:09:50 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)