DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 17, 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 trial of mRNA-1273 (NCT04470427) to ensure that:

a. any and all adverse events and reactions will be documented for the entire duration of the trial;

b. such documenting of adverse events and reactions shall last at least twelve months for adults, thirty-six months for children, and sixty months for infants and toddlers;

c. it uses an adequate sample size, appropriately powered, in order to (i) detect an increase in rare adverse events or any untoward medical occurrence, whether or not considered vaccine related, and (ii) determine that the rate of adverse events from the vaccine will not exceed the rate of adverse events known to occur from SARS-CoV-2 in the group under review; and

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

Your submission was received by this office on 08/17/2020 and it was assigned docket number FDA-2020-P-1769. 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: 2020.08.18 09:16:02 -04'00'

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