DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 24, 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 BNT162b (NCT04368728) provide that:

a. Before an EUA or unrestricted license is issued for the Pfizer vaccine, or for other vaccines for which PCR results are the primary evidence of infection, all "endpoints" or COVID-19 cases used to determine vaccine efficacy in the Phase 3 or 2/3 trials should have their infection status confirmed by Sanger sequencing, given the high cycle thresholds used in some trials. High cycle thresholds, or Ct values, in RT-qPCR test results have been widely acknowledged to lead to false positives;

b. All RT-qPCR-positive test results used to categorize patient as "COVID-19 cases" and used to qualify the trial's endpoints should be verified by Sanger sequencing to confirm that the tested samples in fact contain a unique SARS-CoV-2 genomic RNA. Congruent with FDA requirements for a confirmed diagnosis of human papillomavirus (HPV) using PCR, the sequencing electropherogram must show a minimum of 100 contiguous bases matching the reference sequence with an Expected Value (E Value)<10-30 for the specific SARS-CoV-2 gene sequence based on a BLAST search of the GenBank database (aka NCBI Nucleotide database).

Your submission was received by this office on 11/23/2020. It was assigned docket number FDA-2020-P-2225. Please refer to this docket number in future correspondence on this subject with the Agency. Also, 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: 2020.11.25 09:32:47 -05'00'

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

CC: (b) (6) [redacted]