



Food and Drug Administration
Silver Spring MD 20993

October 21, 2020

Aaron Siri
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Sent via email to: aaron@sirillp.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA require that the Phase III trial of Ad26.COV2.S (NCT04505722) be amended to provide 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 twenty-four months for adults, thirty-six months for children and sixty months for infants and toddlers, or such longer duration as appropriate, and in no event end prior to the subject reaching eight years of age;
- 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;
- d. Participants are tested for T-cell reactivity to SARS-CoV-2 pre-vaccination and post-vaccination;
- e. germline transmission tests are conducted for male participants; and
- f. HIV incidence will be “monitored at the end of study and for an appropriate follow-up period” and the trial will “evaluate the levels and distribution of both vector and insert responses in target tissues where HIV acquisition is known to occur.

Your submission was received by this office on 10/16/2020. It was assigned docket number FDA-2020-P-2096. 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 Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)

CC: Elizabeth Brehm (ebrehm@sirillp.com)