DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 30, 2021

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 for reconsideration of the decision of the Commissioner of Food and Drugs Administration in Docket No. FDA-2020-P-2096 regarding Johnson & Johnson/Janssen's COVID-19 vaccine requesting that the FDA:

1. Require Janssen, the sponsor of Ad26.COV2.S, to amend its Phase III clinical trial protocol to provide that::

    a) any and all adverse events and reactions, with the exception of minor reactions, 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 the 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."

This petition was received by this office on 03/23/2021. Please refer to docket number FDA-2020-P-2096 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 the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby

Digitally signed by Dynna Gorham-Bigby
Date: 2021.03.30 16:00:37 -04'00'

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