DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 11, 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 that FDA study design for the Phase III trials of AZD1222 and ChAdOx1 nCoV-19 (NCT04400838 and NCT04516746)2 be amended to provide that:

- 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"

Your request was received by this office on 09/11/2020 and was assigned docket number FDA-2020-P-1871. 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: 2020.09.14 09:07:36 -04'00'

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