Our Reference: IND 23522

ADVICE
February 16, 2022

AstraZeneca Pharmaceuticals LP
Attention: Elizabeth Daglish
One MedImmune Way
Gaithersburg, MD 20878

Dear Ms. Daglish

Please refer to your Investigational New Drug Application (IND) 23522 submitted under section 505(i) of the Federal Food, Drug, and Cosmetic (FD&C) Act for AZD1222, "Human Coronavirus, Recombinant (Chimpanzee Adenovirus Vector Expressing SARS-CoV-2 Spike Protein; Human Cytomegalovirus Promoter; Replication Defective; E1 and E3 gene deletion, T-Rex-293 Cells) Vaccine," for the prevention of COVID-19 disease.

Please also refer to the following amendments to your IND:

submitted and received on April 28, 2021
submitted and received on May 14, 2021
submitted and received on May 20, 2021
submitted and received on June 04, 2021
submitted and received on June 25, 2021
submitted and received on July 08, 2021
submitted and received on July 16, 2021
submitted and received on July 28, 2021
submitted and received on August 20, 2021
submitted and received on September 13, 2021
submitted and received on September 21, 2021
submitted and received on December 13, 2021
submitted and received on December 23, 2021
submitted and received on February 07, 2022

Based on our review of the available data and information for AstraZeneca's ChAdOx1 nCOV19 vaccine drug substance (DS) lots 21003357, 21003896, 21003900 and 21003971 and the manufacturing conditions of the Emergent Manufacturing Operations Baltimore, LLC (EMOB) Bayview facility during the time period in which these lots were manufactured, FDA has determined that the EMOB facility was not operating in substantial conformity with Current Good Manufacturing Practice requirements during the relevant time period. We understand, however, that you would like to export these lots or vaccine manufactured from these lots. FDA has reviewed facility records, risk assessments, and the results of in-process and release testing for these lots and

determined that lots 21003357, 21003896, 21003900 and 21003971 are acceptable for use, considering the current COVID-19 public health emergency.

We note that although the export of these lots does not fit within any of the applicable exemptions for the export of an unapproved biological product under the FD&C Act, FDA does not intend to object to the export of DS lots 21003357, 21003896, 21003900 and 21003971, or product made from these lots provided that: the agreed upon information sheet is included with each pallet of AstraZeneca's ChAdOx1 nCOV19 vaccine that is exported in sufficient quantities to provide one copy per carton; the instructions regarding the information sheet are included for those who receive the shipments; and you agree that an unredacted version of the fourth addendum to the August 6, 2021 memo *Disposition of AstraZeneca (AZ) AZD1222 Drug Substance (DS) Lots 21002248, 21002635, and 21002636* can be posted on FDA's website. This statement only refers to lots 21003357, 21003896, 21003900 and 21003971 and does not refer to any other lots manufactured at this facility, nor does it cover vaccine manufactured by combining these lots with different lots of drug substance that FDA has not previously determined to be acceptable for use.

If you have any questions, please contact the Regulatory Project Manager, Laura Montague by phone (240-204-4519) or email (Laura.Montague@fda.hhs.gov).

Sincerely,

Peter Marks, M.D. Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research