



Our Reference: IND 23522

ADVICE
August 6, 2021

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 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 your amendments submitted to your IND

- submitted and received on February 17, 2021
- submitted and received on April 7, 2021
- submitted and received on April 09, 2021
- 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 03, 2021
- submitted and received on June 04, 2021
- submitted and received on June 07, 2021
- submitted and received on June 16, 2021
- submitted and received on June 25, 2021
- submitted and received on July 08, 2021
- submitted and received on July 28, 2021

Based on our review of the available data and information for AstraZeneca's ChAdOx1 nCoV19 vaccine drug substance (DS) lots 21002248, 21002635, and 21002636 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 the

21002248, 21002635, and 21002636 lots 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 21002248, 21002635, and 21002636, 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, instructions regarding the information sheet are included for those who receive the shipments, and you agree that an unredacted version of 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 the above listed lots, 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,

If you have any questions, please contact the (b) (6)
(b) (6)

Sincerely,

Marion Gruber, PhD
Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research