December 13, 2024

AstraZeneca Pharmaceuticals LP
Attention: Lei Hua, PhD, PMP, RAC
Associate Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Re: Revocation of EUA 104

Dear Dr. Hua:

This letter is in response to the request from AstraZeneca Pharmaceuticals LP (AstraZeneca), received on November 21, 2024[1], that the U.S. Food and Drug Administration (FDA) revoke the EUA for EVUSHELD (tixagevimab co-packaged with cilgavimab). The EUA for EVUSHELD was issued initially on December 8, 2021. AstraZeneca has informed the FDA that all lots of EVUSHELD manufactured, labeled and distributed for use under EUA 104 have expired and that AstraZeneca does not intend to offer this product in the United States anymore. FDA understands that AstraZeneca will issue a communication to notify customers and providers that have received EVUSHELD under the EUA of this revocation with instructions for product destruction or return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with EVUSHELD, because FDA understands that AstraZeneca no longer intends to offer EVUSHELD in the United States under the EUA; because all product manufactured, labeled, and distributed pursuant to the EUA has expired; and because AstraZeneca has requested that FDA revoke the EUA for EVUSHELD, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 104 for EVUSHELD pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, EVUSHELD is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

[1] At the time of AstraZeneca's request, EVUSHELD was not authorized for emergency use in the United States due to the high frequency of circulating SARS-CoV-2 variants that are non-susceptible to EVUSHELD.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2024.12.13 10:47:28 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration