EUA 118

EMERGENCY USE AUTHORIZATION

InflaRx GmbH
c/o Dunn Regulatory Associates, LLC
Attention: Dana Dunn, MS
President, Dunn Regulatory Associates, LLC
2709 Silkwood Court
Oakton, VA 22124

Dear Dana Dunn:

Please refer to your Emergency Use Authorization (EUA) for GOHIBIC (vilobelimab) for the treatment of coronavirus disease 2019 (COVID-19) in certain hospitalized adults, initially issued on April 4, 2023, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer to your September 26, 2025, submission (eCTD 0074) to EUA 118 requesting a shelf-life extension for the following drug product (DP) lots manufactured in accordance with the EUA:

- A 48-month shelf-life for DP lots manufactured by Process 4 at WuXi Biologics, Germany (FEI # 302002803) from Lot 20230301-1 onwards.

We have completed our review and concur with the request described above.

By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the April 12, 2023, letter[1] authorizing the emergency use of GOHIBIC (vilobelimab) for the treatment of coronavirus disease 2019 (COVID-19) in certain hospitalized adult patients.

[1] The Letter of Authorization was initially issued on April 4, 2023 and was subsequently reissued on April 12, 2023

If you have any questions, contact Kristi De Lisle, MS, BSN, RN, Regulatory Business Process Manager, at Kristi.Delisle@fda.hhs.gov or (301) 796 - 8013.

Sincerely,

{See appended electronic signature page}

Rapti Madurawe, PhD for
Susan Rosencrance, Ph.D.
Deputy Office Director
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research