DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

June 12, 2025

Octapharma Pharmazeutika Produktionsges.m.b.H.
Attention: Sergio Alegre
Octapharma USA, Inc.
117 West Century Road
Paramus, NJ 07652

Dear Sergio Alegre:

This letter is in response to your amendment received May 28, 2025, and further amended June 2, 2025, to your EUA for octaplasLG Powder (blood group types A and AB) for use by U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

We have reviewed the requested changes and information to support the revisions to your Authorized Fact Sheets and WFI label, and your request is granted.

We concur with your request to implement the inclusion of a transfusion filter set to comply with Condition F of the EUA Letter of Authorization.

We concur with the updates to the EUA Fact Sheet for Health Care Professionals or Other Authorized Providers to include the following new information:

**Product Administration**

1. Always use aseptic technique when connecting the transfusion set with the vented spike adaptor and the vial.

2. Remove the blister from the transfusion set and the blister from the vented spike adaptor.

3. Remove the protective cap from the spike of the transfusion set. Slide the vented spike adaptor on the spike of the transfusion set. Then remove the protective cap from the spike of the adaptor.

4. Connect the transfusion set with the adaptor to the powder bottle (octaplasLG Powder) by perforating the rubber stopper centrally with the spike of the adaptor.

5. Ensure the spike is fully inserted into the vial so that liquid can flow through the tubing.

6. Gently squeeze the drip chamber of the transfusion set to fill it partially with liquid.

7. Transfuse the product according to your established clinical protocols. Patients' vital signs should be closely monitored throughout the infusion as conditions permit.

8. Repeat administration as medically necessary.

**Risks and Adverse Events:**

- Transfusion-related acute lung injury has been reported spontaneously in patients receiving octaplasLG and other blood products.

The EUA Fact Sheet for Healthcare Providers Professionals or Other Authorized Providers has also been updated to include other minor editorial changes.

We also concur with the update to the EUA Fact Sheet for Recipients and Caregivers to clarify that a lung injury associated risk of receiving octaplasLG Powder includes transfusion-related acute lung injury.

Finally, we concur with the use of the approved European WFI label for the co-packed WFI bag. The approved European WFI bag label is supplied in one of four language clusters (i.e., label versions), as outlined below:

| Cluster | Languages | Country assignment |
|---|---|---|
| **1** | German, French, Dutch, English | AT, BE, FR, IE, NL, MT, UK, LU, CH, USA |
| **2** | Spanish, English | ES, IE, MT, UK, USA |
| **3** | Bulgarian, Czech, Croatian, Hungarian, English | BG, CZ, HR, IE, HU, MT, UK, USA |
| **4** | Danish, Finnish, Norwegian, Swedish, English | DK, FI, NO, IE, SE, MT, UK, USA |

By submitting this amendment for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the August 8, 2024, letter authorizing the emergency use of octaplasLG Powder.

If you have any questions, please contact LCDR Kimberly Bissohong, Team Lead, Regulatory Project Management Staff, at Kimberly.Bissohong@fda.hhs.gov or (301) 796-5350.

Sincerely,

Anne Eder, MD, PhD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research