



August 29, 2023

Emily D. Badraslioglu,
Office of Regulated Activities
Office of the Surgeon General, Department of the Army
U.S. Army Medical Research and Development Command
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Re: EUA 17986 - Emergency Use Authorization of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma (Centre de Transfusion Sanguine des Armées) Issued on July 9, 2018, under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3); Amendment granted on May 8, 2020 included, where needed, removing the term “Pathogen-Reduced”.
Request in Amendments submitted and received on March 2, 2023 (initial amendment request); July 20, 2023 (final amendment) to update authorized Fact Sheet for U.S. Military Medical Personnel

Dear Ms. Badraslioglu,

This letter is to notify you that we have reviewed the requested changes and data to support: 1) a change to the volume of Centre de Transfusion Sanguine des Armées Leukocyte-Depleted Freeze Dried Plasma (French FDP) and sterile water for injection for a single batch of French FDP kits, and 2) an update to the authorized EUA Fact Sheets and authorized EUA labeling to reflect these changes, and that your request has been granted.

Upon review, we concur with your request to use a single batch of the French FDP manufactured from a larger volume of plasma to permit reconstitution with a larger volume of sterile water (250 mL) compared to the original kit configuration (200 mL). We also concur with 1) the related updates of the Fact Sheet for U.S. Military Medical Personnel for the authorized French FDP to clarify that the product may be reconstituted with either 200 mL or 250 mL, and a caution that the plasma bottle must be reconstituted with the volume of water indicated on the plasma bottle label; and 2) a plasma bottle label for this lot of French FDP that indicates that 250 mL of sterile water for injection must be used for reconstitution.

Other minor changes were also made to the Fact Sheet for U.S. Military Medical Personnel and the Fact Sheet for Recipients.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the July 9, 2018, letter authorizing the emergency use of Leukocyte-Depleted Freeze-Dried Plasma.

Sincerely,

Anne Eder, M.D., Ph.D.
Acting Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research