



May 8, 2020

Mark S. Paxton, JD, MS
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 - Requests for Amendments to Authorize a New Plasma Source and Update the Authorized Fact Sheets and Labeling
Product Name: Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma (“French FDP”)
Dated: March 1, 2019 (initial amendment request); April 22, 2020 (complete amendment request)
Received: March 1, 2019 (initial amendment request); April 22, 2020 (complete amendment request)

Dear Mr. Paxton:

This letter is to notify you that your requests to (1) allow French FDP to be manufactured from certain French-sourced or United States-sourced plasma and (2) update the authorized EUA Fact Sheets and authorized EUA labeling to clarify the use of either plasma source for the authorized French FDP under the July 9, 2018, [EUA](#) have been granted.

Upon review, we concur that the additional data that DoD submitted for EUA 17986 support the use of either pooled French-sourced, pathogen-reduced (INTERCEPT™-treated) apheresis plasma or pooled United States-sourced, FDA-licensed apheresis plasma in the manufacture of French FDP. We also concur with the related updates of the EUA Fact Sheets for the authorized French FDP to clarify that French FDP may be manufactured from either of these authorized plasma sources. In addition, we concur with the source of plasma (i.e., either French-sourced or U.S.-sourced) being identified in the EUA labeling of the final product.¹

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 French FDP.

¹ This includes, where needed, removing the term “pathogen-reduced.”

Sincerely,

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Nicole Verdun, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosures:

Fact Sheet for U.S. Military Medical Personnel
Fact Sheet for Recipients