U.S. FOOD & DRUG ADMINISTRATION

June 15, 2023

Mike Druckman
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Sent via email to: mike.druckman@hoganlovells.com

Re: Citizen Petition – Docket Number FDA-2022-P-3318

Dear Mr. Druckman:

I am writing to inform you that the Food and Drug Administration (FDA, we) has not yet reached resolution of the issues raised in the citizen petition you submitted on behalf of Octapharma USA, Inc., and Octapharma Pharmazeutika Produktionsge mbH received by the Dockets Management Staff on December 21, 2022. In the petition, you request FDA take the following actions:

1. Set aside the Biologics License Applications for blood products licensed to Central California Blood Center, Community Blood Center, Inc. in Appleton, Wisconsin, and Gulf Coast Regional Blood Center and manufactured using the INTERCEPT Blood System because:

    a. These fibrinogen products are manufactured by chemical means beyond the physical and mechanical manipulations required for products regulated as blood components;

    b. Their regulation as blood components rather than blood derivatives is in contravention of FDA regulations and historic practice; and

    c. These products have not been established to be safe, pure, and potent through rigorous clinical studies as required by the Public Health Service Act.

2. Refrain from licensing any additional fibrinogen products manufactured with the INTERCEPT Blood System as blood components for the same reasons.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request. Per our agreement, FDA will respond to your petition by June 21, 2023.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Sincerely,

Peter Marks

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff

U.S. Food & Drug Administration
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