December 22, 2022

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

Dear Petitioner:

Your submission requesting that the Commissioner take the following actions:

1. Set aside the BLAs for blood products licensed to the Blood Centers 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's 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 (PHSA).

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

Request was received and processed under CFR 10.30 by this office on 12/21/2022 and assigned docket number FDA-2022-P-3318. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S Digitally signed by Karen P. Malvin -S Date: 2022.12.22 14:10:21 -05'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

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