July 5, 2022

Leonard A. Valentino, MD, President & Chief Executive Officer
National Hemophilia Foundation
7 Penn Plaza, Suite 1204
New York, NY 10001

Sent via email to: jgray@artemispolicygroup.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug require a REMS as a condition of approving valoctocogene roxaparvovec and etranacogene dezaparvovec, also include the eligibility (inclusion and exclusion) criteria utilized in the clinical trials on the drug label was received and processed under CFR 10.30 by this office on 07/01/2022.

It was assigned docket number FDA-2022-P-1444. 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: 2022.07.05 10:08:29 -04'00'

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