DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

July 21, 2020

Scott M. Lassman, Principal
Lassman Law + Policy
1717 K Street, N.W., Suite 900
Washington, DC 20006

Sent via email to: scott@lassmanfdalaw.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to refuse to issue a license to RYONCIL for the treatment of SR-aGVHD in pediatric patients unless and until the sponsor provides "substantial evidence"of effectiveness that consists of, at a minimum, at least one successful, pivotal clinical trial that is prospective, randomized, blinded, and uses an appropriate concurrent control; and Provide a copy of this Citizen Petition to members of any Advisory Committee scheduled to discuss the BLA for RYONCIL for the proposed indication for treatment of SR-aGVHD in pediatric patients was received by this office on 07/20/2020.

It was assigned docket number FDA-2020-P-1689. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.21 10:12:48 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)