



April 28, 2022

Patrick Girondi
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308 E. Emily St.
Tampa, FL 33603

Sent via email to: megan@sanroccotherapeutics.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug do a careful investigation of the BLA from Bluebird seeking a license for Beti-Cel for the treatment of β -thalassemia was received and processed under CFR 10.30 by this office on 04/28/2022.

It was assigned docket number FDA-2022-P-0704. 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 Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)