



December 23, 2022

Sent via mail to:

Allain A. Roy
Senior Citizen

(b) (6)

Dear Petitioner:

Your submission requesting that the FDA immediately grant Breakthrough Therapy Designation (BTD) for Simufilam (formerly PT1-125) sponsored by Cassava Sciences was received and processed under CFR 10.30 by this office on 12/20/2022.

It was assigned docket number FDA-2022-P-3321. 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)