



**FDA U.S. FOOD & DRUG**  
ADMINISTRATION

December 22, 2022

Michael K. Law

(b) (6)

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug immediately grant Breakthrough Therapy Designation (BTD) for Simufilam (formerly PTI-125) sponsored by Cassava Sciences was received and processed under CFR 10.30 by this office on 12/22/2022.

It was assigned docket number FDA-2022-P-3320. 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)