



August 8, 2022

Huang Jingshan, Vice President
Reyoung Pharmaceutical Co., Ltd.
No. 1, Ruiyang Road
Yiyuan County, Shandong Province, China

Sent via email to: wangying@hqdds.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug declare that the proposed drug product Posaconazole for delayed-release oral suspension, USP, 100 mg is suitable for submission as an Abbreviated New Drug Application was received and processed under CFR 10.30 by this office on 08/08/2022.

It was assigned docket number FDA-2022-P-1833. 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)

CC: wang.shijun@reyoung.com