May 18, 2022

Lu Lin, Ph.D.
ApicHope Pharmaceuticals (USA) Limited
3500 South DuPont Hwy.
Dover, DE 19901

Sent via email to: 21500001@gdyph.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether RS CEFDINIR powder for suspension (125 mg/5 mL; 250 mg/5 mL) approved under ANDA 0653337 was discontinued or withdrawn for safety or effectiveness reasons and to designate an additional RS was received and processed under CFR 10.30 by this office on 05/18/2022.

It was assigned docket number FDA-2022-P-0833. 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 P. Malvin -S

Digitally signed by Karen P. Malvin -S
Date: 2022.05.18 13:41:25 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)