



June 7, 2022

Xiaofeng Meng, Chief Executive Officer
Epic Pharma, LLC
227-15 N. Conduit Ave.
Laurelton, NY 11413

Sent via email to: RADept@epic-pharma.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine that the drug product, Bupirone Hydrochloride Tablets, USP, in the new strengths of 2.5 mg, 3.75 mg, and 12.5 mg per tablet, is suitable for submission in an ANDA was received and processed under CFR 10.30 by this office on 06/07/2022.

It was assigned docket number FDA-2022-P-1039. 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)