



August 18, 2022

Michael Eastep, Director Project Management & US Representative
Suven Pharmaceuticals Limited
1100 Cornwall Road
Monmouth Junction, NJ 08852

Sent via email to: meastep@suvenpharm.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug declare that Glycopyrrolate Oral Film, in strengths of 1 mg, 1.5 mg and 2 mg are suitable for submission as an ANDA was received and processed under CFR 10.30 by this office on 08/16/2022.

It was assigned docket number FDA-2022-P-1938. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability 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)