DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 8, 2020

A. Renuka Devi
GLAND PHARMA LIMITED
D.P. Pally, Dundigal, Medchal-Malkajgiri District,
Hyderabad 500043, Telangana, India

Sent via email to: renuka.achanta@glandpharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA declare that the drug product, Doxercalicferol Injection,10 mcg/5 mL (2 mcg/mL) is suitable for submission and review as a Prior Approval supplement (PAS) for already approved ANDA pursuant to section 5050) of the Federal Food, Drug and Cosmetic Act, as amended was received by this office on 09/04/2020.

It was assigned docket number FDA-2020-P-1859. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.09 09:51:29 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations

Cc: gland@glandpharma.com