Gland Pharma Limited
Attn: A. Renuka Devi
D.P. Pally, Dundigal, Medchal-Malkajgiri District,
Hyderabad 500043, Telangana, India

Docket No. FDA-2020-P-1859

Dear A. Renuka Devi:

This is in response to your petition received on September 8, 2020, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Doxercalciferol Injection, 10 mcg/5 mL (2 mcg/mL). The listed drug product to which you refer in your petition is Hectorol® Injection, 4 mcg/2mL (2 mcg/mL), approved under New Drug Application (NDA) 021027 and held by Sanofi Genzyme.

Your petition requests a change in strength (total drug content) from that of the listed drug product (i.e., from Doxercalciferol Injection, 4 mcg/2 mL (2 mcg/mL) to 10 mcg/5 mL (2 mcg/mL). A change in strength is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

However, one of the requirements for approval of a petition under section 505(j)(2)(C) of the Act is that there is not "a drug product approved in an NDA for the change described in the petition." 21 CFR 314.93(e)(1)(vi). Therefore, FDA denies your petition because a drug product is approved in an NDA for the change described in the petition: Doxercalciferol Injection 10 mcg/5 mL (2mcg/mL), approved under NDA 208614, held by Hospira Inc.[1]

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

[1]The Agency notes that NDA 208614 is listed on the Discontinued Drug Product List in FDA's *Approved Drug Product's With Therapeutic Equivalence Evaluations* (the Orange Book). See Orange Book Preface at section 1.11 for more information on the discontinued section of the Orange Book). An ANDA may be submitted that relies on a listed drug approved for safety and effectiveness under section 505(c) of the Act but has been voluntarily withdrawn from sale in the United States. See 21 CFR 314.122(a). Please note, however, that a determination whether an RLD has been withdrawn for safety or effectiveness reasons must be made before FDA may approve an ANDA that refers to an RLD on the Discontinued Drug Product List. 21 CFR 314.161(a).

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0014334738, cn=William H. Chong -S
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William Chong, M.D.
Associate Director of Clinical Affairs
for Iilun Murphy, M.D.
Deputy Director for Clinical and Regulatory Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov