October 03, 2022

Office of Generic Drugs (HFD-600),
Center for Drug Evaluation and Research,
Food and Drug Administration,
10903 New Hampshire Avenue,
Silver Spring, MD 20993.

ANDA # 217652
INFORMATION REQUEST
QUALITY
Sequence # 0004

Kind Attention: Filita Long

Subject: Hydroxyzine Hydrochloride Tablets, USP 10 mg, 25 mg and 50 mg. (ANDA# 217652) – Information Request Quality.

Respected Sir / Madam,

This is in response to the Agency's Information Request Quality dated September 27, 2022 issued for the subject Abbreviated New Drug Application (ANDA). Graviti Pharmaceuticals Private Limited is amending their application by submitting response to the Agency's comments.

The Agency's comment is reproduced in bold and italics followed by our response.

A. Manufacturing:

a. Facility

Please note that there is a facility (e.g. DS manufacturing, intermediate, or release/stability testing sites) included in DMF (DMF 019596 for HYDROXYZINE HYDROCHLORIDE) that was not included on your form 356h. Please contact your DMF holder to resolve any discrepancies and clarify which DMF related facilities support your application. Please note that a revised 356h form will be required to add any new facilities to your application. Module 3 should also be updated as appropriate. The addition of a new facility or new facilities may result in an extension of the performance goal date for your submission.

Response:

Based on the agency's comment, we contacted the DMF holder, M/s. Symed Labs Limited, regarding the above said query. DMF holder confirmed that they are manufacturing the API in Unit-2 and Unit-4 and no other sites being used for Manufacturing & Testing of Drug substance and no updates in the manufacturing section 3.2.S.2 .1.

However, Graviti Pharma utilised API manufactured from Symed Labs Limited, Unit-II for exhibit batches and also proposed same for intended commercial manufacturing. Accordingly, the information related to Symed Labs Limited, Unit-II included in section 3.2.S.2.1 and form 356h, supporting LOA with specific site was provided in 1.4.2 section of original submission.

This is to inform the agency that Graviti Pharmaceuticals Private Limited has verified that the proposed change (s) described in this amendment is not one of the types of amendment described in 21 CFR 314.96 (d)(1).

Please contact the undersigned at Freyr, Inc. 150 College Road West, Suite 102, Princeton NJ 08540, USA, Phone: +1 908 483 7958; Extn: 3021, Fax: +1 866 486 6883,
E-mail: Akshaya.K@FreyrSolutions.com

Sincerely yours,

Akshaya Krishnamoorthy
US Agent for Graviti Pharmaceuticals Private Limited.