



NDA 013263/S-101

**APPROVAL LETTER**

Waylis Therapeutics LLC  
c/o Parexel International  
Attention: Nupur Dutta Chowdhury, Regulatory Affairs Consultant  
2520 Meridian Parkway, Suite 200  
Durham, NC 27713

Dear Ms. Dutta Chowdhury:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 25, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Valium (diazepam) tablets.

This “Changes Being Effected” supplemental new drug application provides for the insertion of carton packaging, a tertiary packaging component of Valium (diazepam) Tablets, 5mg.

**APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on September 25, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 013263/S-101.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

*{See appended electronic signature page}*

Gurpreet Gill-Sangha, Ph.D., Supervisor  
Division of Product Quality Assessment II  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Gurpreet  
Gill Sangha

Digitally signed by Gurpreet Gill Sangha

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