NDA 209241/S-028

SUPPLEMENT APPROVAL

Neurocrine Biosciences Inc.
Attention: Rylan Hanks
Executive Director Regulatory Affairs
12780 El Camino Real
San Diego, CA 92130

Dear Mr. Hanks:

Please refer to your Supplemental New Drug Application (sNDA) dated May 23, 2024, received May 23, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ingrezza (valbenazine tosylate) capsules.

We also refer to our approval letter dated November 22, 2024, which contained the following error: The carton and containers labels were not attached to the letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain November 22, 2024, the date of the original approval letter.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 the enclosed carton and container labels submitted on August 13, 2024, and September 11, 2024, 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 209241/S-028.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (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 Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 12/04/2024 09:02:23PM
GUID: 5135f2ad000117842392c50c36c7f28a