NDA 208082/S-008

**SUPPLEMENT APPROVAL**

Teva Branded Pharmaceutical Products R&D, Inc.
Attention: Angela Randall
Director, Regulatory Affairs Labeling
145 Brandywine Parkway
West Chester, PA 19380

Dear Ms. Randall:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 13, 2020, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Austedo (deutetrabenazine) Tablets, 6 mg, 9 mg, and 12 mg.

This Prior Approval supplemental new drug application provides for addition of a new physician sample package configuration that expands the currently approved 2-week titration pack to include a 4-week titration kit.

## 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 enclosed carton and container labels, 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 208082/S-008.**" 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 Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

*{See appended electronic signature page}*

David Lewis, Ph.D.
Branch Chief, Branch 2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Carton and Container Labeling