NDA 021882/S-037

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Andrew Bridge
Regulatory CMC Associate Director - Regulatory Affairs GDD CMC
One Health Plaza
Bldg. 337 - B07.3d
East Hanover, NJ 07936

Dear Mr. Bridge:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 18, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exjade (deferasirox) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

- Addition of (b) (4) as an alternate manufacturing, release testing and (b) (4) testing site of the drug product Exjade®(deferasirox) tablets, with the following consequential changes:
- Change in the batch size (b) (4) of the finished product.
- Minor change in the critical process parameters and critical quality attributes.
- Minor change in the process parameters applied during the manufacture of the finished product.
- Minor change in the non-critical quality attributes and process parameters. applied during the manufacture of the finished product.
- Change in the specification limits of an excipient.

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, 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 021882/S-037." 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 Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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