NDA 021008/S-046

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Elizabeth Marchese
Regulatory CMC Senior Manager - Regulatory Affairs GDD CMC
One Health Plaza, Building 337
East Hanover, NJ 07936

Dear Ms. Marchese:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 19, 2022, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sandostatin LAR Depot (octreotide acetate) for injectable suspension.

This Prior Approval supplemental new drug application provides for the addition of (b) (4) as an alternate site for the manufacture and quality control of octreotide acetate drug substance as referenced by NDA 019667/S-075.

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 and carton and container labels submitted on November 22, 2022, 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 021008/S-046.**" 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 Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch 1
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