NDA 21106/S-045

APPROVAL LETTER

Pharmacia & Upjohn Company, a subsidiary of Pfizer Inc.
Attention: Gurunandan Mavinkurve
Director, Global Regulatory Affairs
235 East 42nd Street (219/9/81)
New York, NY 10017

Dear Mr. Mavinkurve:

Please refer to your Supplemental New Drug Application (sNDA) dated November 11, 2014 and received November 12, 2014, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Somavert (pegvisomant) for injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for labeling to correct discrepancies between the Description Section in Package Insert in PAS N021106/S-044 and the drug product composition for introduction of 25 mg and 30 mg/vial strengths of the product.

We have completed our review of this supplemental new drug application. This supplement is approved.

The content of labeling in this supplement has been superseded by the content of labeling approved in S-064 on September 19, 2019. Therefore, the content of labeling in this supplement (S-045) will not be reviewed.

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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

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

Ramesh Raghavachari

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