BLA 021426/S-050

APPROVAL LETTER

Sandoz Inc
Attention: Jackline George
Manager Biopharma Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Ms. George:

Please refer to your supplemental biologics license application (sBLA) dated and received September 30, 2021, submitted under section 351(a) of the Public Health Service Act for Omnitrope (somatropin) injection.

This Prior Approval sBLA provides for addition of a protocol (b) (4) (b) (4) at Sandoz, Kundl, Austria, to allow for reporting in the Annual Report.

APPROVAL

We have completed our review of this sBLA. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, call Kristine Leahy, Regulatory Business Process Manager, at (240) 402 - 5834.

Sincerely,

{See appended electronic signature page}

Gibbes Johnson, Ph.D.
Director
Division of Biotechnology Review and Research IV
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gibbes Johnson

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