



NDA 19-774/S-009

Savient Pharmaceuticals, Inc.
Attention: Briti Kundu
Senior Director, Regulatory Affairs
One Tower Center, 14th Floor
East Brunswick, NJ 08816

Dear Ms. Kundu:

Please refer to your supplemental new drug application dated November 11, 2004, received November 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tev-Tropin (somatropin for injection).

We acknowledge receipt of your submission dated February 3, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions to the CONTRAINDICATIONS and WARNINGS sections of the package insert regarding use in Prader-Willi patients, in response to our letter dated August 2, 2004.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 11, 2004 (vial labels for growth hormone, vial labels for diluent, patient package insert, carton for 2-vial presentation, carton for 6 X 2-vial presentation) and February 3, 2005 (package insert).

However, at the next printing, please correct the following errors in the package insert:

- In CONTRAINDICATIONS, the first sentence, "inpatients" should be "in patients".**
- In WARNINGS, the first sentence, "Prader-willi" should be "Prader-Willi", "sybdrome" should be "syndrome", and "sever" should be "severe".**

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kati Johnson, Chief, Project Management Staff, at (301) 827-6380.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert)

**This is a representation of an electronic record that was signed electronically and
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/s/

David Orloff
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