



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-075/S-008

Genentech, Inc.
Attention: Cathy Sueoka-Lennon
Senior Associate, Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-4990

Dear Ms. Sueoka-Lennen:

Please refer to your supplemental new drug application dated March 11, 2004, received March 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nutropin Depot® (somatropin [rDNA origin] for injectable suspension).

We acknowledge receipt of your submission dated October 5, 2004, which constituted a complete response to our September 10, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions to the CONTRAINDICATIONS and WARNINGS sections of the package insert regarding the treatment in Prader Willi patients, in response to our letters dated December 12, 2003 and March 30, 2004.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

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 (Identifier 4819505, Code Revision Date October 2004)

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

David Orloff
10/20/04 02:17:30 PM