DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-522/S-027

Genentech, Inc.
Attention: Robert Garnick, Ph.D.
Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Garnick:

Please refer to your supplemental new drug application dated January 21, 2005, received January 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nutropin AQ [somatropin (rDNA origin) injection].

We acknowledge receipt of your submissions dated June 28 and November 14 (email), 2005.

This supplemental new drug application provides for the addition of new information to the **CLINICAL STUDIES**, Adult Growth Hormone Deficiency (GHD) subsection of the Nutropin AQ package insert describing the effects of somatropin on visceral adipose tissue in the adult growth hormone deficient patient population.

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 agreed-upon labeling text and with the minor editorial revisions listed below.

> Replace the section heading "**EFFICACY STUDIES**" with "**CLINICAL STUDIES**" to be in compliance with 21 CFR 201.57(m).

The final printed labeling (FPL) must be identical to the enclosed labeling, which includes the minor editorial revision indicated above to the text for the package insert submitted November 14, 2005, by email. This revision is a term of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-522/S-027**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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).

If you have any questions, call Kati Johnson, Chief, Project Project Management Staff, (301) 796-1234.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

11/18/2005 10:39:42 AM