DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-676/S-030
NDA 20-522/S-033

Genentech, Inc.
Attention: Jane Chiang, MD
Senior Scientist, Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Chiang:

Please refer to your supplemental new drug applications dated June 29, 2006, received June 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nutropin (somatropin [rDNA origin] for injection, and Nutropin AQ (somatropin [rDNA origin] injection, respectively.

We acknowledge receipt of your submissions dated July 13, 2006, to both applications.

These supplemental new drug applications provide for harmonization of labeling across somatropin applications, primarily involving the CONTRAINDICATIONS and PRECAUTIONS sections of the package insert.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 29, 2006.

However, at the next printing, revise the package insert as follows:

1. Delete reference to "long term" with respect to treatment for any indication, since this terminology is not used with other products given for chronic use.
2. In the following sentence in the CONTRAINDICATIONS section, delete the hyphen in "pre-existing": "Any pre-existing malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin."
3. In the DOSAGE AND ADMINISTRATION section, Adult Patient subsection, delete "more" from the following sentence: "Alternatively, taking into account more recent literature, a starting dose of approximately 0.2 mg/day…"
4. In the PRECAUTIONS section, Laboratory Tests subsection, modify the section to include the underlined text and to delete the ~~strikethrough~~ text: "Serum levels of inorganic phosphorus, alkaline phosphatase, ~~and~~ parathyroid hormone (PTH) and IGF-1 may increase during somatropin therapy.

5. In the PRECAUTIONS section, Information for Patients subsection, add the following text: "See WARNINGS for use of Bacteriostatic Water for Injection, USP, (benzyl alcohol preserved), in newborns." (**Nutropin package insert only**). This should be the last sentence in that section.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:
Nutropin Package Insert: 7123911 (4834502), Revision Date June 2006
Nutropin AQ Package Insert: 7318904 (4834601), Revision Date June 2006

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

/s/

Mary Parks

2/15/2007 10:35:02 AM