NDA 20-522/S-009

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

Dear Dr. Garnick:

Please refer to your supplemental new drug application dated January 29, 1999, received February 1, 1999, 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 August 11, October 29, and November 5, 1999.

This supplemental new drug application provides for the following additions to the CLINICAL PHARMACOLOGY section of the labeling: (1) improvement in spine bone mineral density observed in childhood-onset adult growth hormone deficient patients; and (2) increases in serum alkaline phosphatase.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

You are not required to complete a pediatric assessment for this application because it is not covered by the Pediatric Rule (21 CFR 314.55(a)).

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 5, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20522/S-009." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Crystal King, P.D., M.G.A., Regulatory Project Manager, at (301) 827-6423.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure