DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-676/S-020, S-021
NDA 20-522/S-021, S-022

Genentech, Inc.
Attention: Pat Harada
Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-4990

Dear Ms. Harada:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following applications:

NDA 19-676/S-020, S-021, Nutropin (somatropin (rDNA origin) for injection)
NDA 20-522/S-021, S-022, Nutropin AQ (somatropin (rDNA origin) injection)

NDA 19-676/S-020 and NDA 20-522/S-021 provide for the addition of long-term treatment of idiopathic short stature as an indication.

NDA 19-676/S-021 and NDA 20-522/S-022 provide for revisions to the CONTRAINDICATIONS and WARNINGS sections of the package insert regarding the treatment of Prader Willi Patients.

We also refer to our June 28, 2005 approval letters in which we inadvertently omitted a description of your plan to address the potential for inappropriate use in patients who either do not meet the indicated criteria for treatment or who have not undergone a thorough diagnostic evaluation.

You will receive a corrected action letter, where the action date will be unchanged; however, the signature time will be one minute later to allow differentiation between the two letters.

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

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

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