DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-522/S-026, S-036, S-037

Genentech, Inc.
Attention: Suzanne Kiani
Scientist, Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080-490

Dear Ms. Kiani:

Please refer to your supplemental new drug applications dated November 18, 2004 (S-026), February 21 (S-036) and 28 (S-037), 2007, received November 22, 2004 (S-026), February 22 (S-036) and March 5, 2007 (S-037) under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nutropin AQ (somatropin [rDNA origin] injection).

We acknowledge receipt of your following submissions:

1. Supplement -026: June 8, August 6, and October 10, 2007. Your submission of June 8, 2007 constituted a complete response to our May 12, 2005 action letter.
2. Supplement -036: May 15 and 16, and November 19, 2007.
3. Supplement -037: May 15 and 16, August 6, and November 19, 2007

These supplemental new drug applications provide for the following:
-Supplement -026: provides for a new strength drug product, Nutropin AQ 20 mg cartridge (20 mg/2 mL), and a new reusable multi-dose delivery device, **Nutropin AQ Pen 20**, to be used specifically with the Nutropin AQ Pen 20 mg cartridge.

-**Supplement -036:** provides for a disposable multi-dose, dial-a-dose, injection device prefilled with the currently approved Nutropin AQ 10 mg/2 mL (5 mg/mL) cartridge. Tradename=Nutropin AQ NuSpin 10**.**

-Supplement -037: provides for two new strength cartridges, 5 mg/2 mL (2.5 mg/mL), and 20 mg/2 mL (10 mg/mL) contained in respective injection delivery systems (identical to that proposed in S-036). Tradename=Nutropin AQ NuSpin 20**.**

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. Final printed labeling has been submitted for all labeling except the package insert.

CONTENT OF LABELING

Package Insert

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplemental NDA 20-522/S-026, S-036, S-037."

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 reporting requirements for an approved NDA (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 & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Labeling
Common to all 3 supplements:
-Package Insert

Supplement -026
-cartridge label (4833000)
-cartridge tyvek lidstock labeling (4833100)
-cartridge carton labeling (4832900)
-pen folding carton (4832700)
-pen case labeling (4832500)
-Instructions for Patient/Parent (4831700)

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
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