DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-280/S-038

Pharmacia & Upjohn Company
Attention: James Balun
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Balun:

Please refer to your supplemental new drug application dated December 28, 2001, received December 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection) 1.5, 5.8, and 13.8 mg.

We acknowledge receipt of your submission dated November 25, 2002.

Your submission of November 25, 2002, constituted a complete response to our April 30, 2002, action letter.

This supplemental new drug application provides for an alternate manufacturing facility, (b)(4) (b)(4)----------, for the drug product in two-chamber Intra-Mix cartridges, 1.5 mg, 5.8 mg, and 13.8 mg.

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.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted November 25, 2002, Directions for Use insert submitted November 25, 2002, two-chamber Intra-Mix cartridge labels submitted November 25, 2002, and pre-assembled Intra-Mix device carton labels submitted November 25, 2002).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 20-280/S-038.**" Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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 Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
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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