DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-106/S-015

Pfizer Inc.
Agent for Pharmacia & Upjohn
Attention: Ben Drosman
US Regulatory Affairs
235 East 42nd street
New York, NY 10017-5755

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated May 22, 2008, received May 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SOMAVERT (pegvisomant for injection).

This "Changes Being Effected" supplemental new drug application provides for the following revisions:

Package Insert

a. Revision of the PRECAUTIONS section to include the statement, "Lipohypertrophy has been reported in <5% of patients following pegvisomant administration."

b. Addition of a Post-Marketing Experience section to include the following text:

   1. "Lipohypertrophy has been reported in <5% of patients following pegvisomant administration."

   2. "Asymptomatic, transient elevations in transaminase up to 15 times ULN have been observed in <2% of patients in the post-marketing experience. These reports were not associated with an increase in bilirubin, and there were no clinical consequences for these patients. Transaminase elevations normalized with time, most often after suspending treatment (SOMAVERT should be used in accordance with the information presented in Table 4 with respect to liver test abnormalities)."

c. The DOSAGE AND ADMINISTRATION section has been revised to include the following statement:
"Pegvisomant may be given in the thigh, buttocks, upper arm, or abdomen; the site of SC injections should be rotated daily to help prevent lipohypertrophy."

Patient Package Insert
This has been revised to include a clarification as to why a different injection site should be used each day (so lumps do not develop).

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 22, 2008.

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, M.D.
Director
Division of Metabolism & Endocrinology 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/

Mary Parks

8/18/2008 12:50:32 PM