DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-106

Pharmacia & Upjohn Company
Attention: Satish C. Tripathi, PhD, RAC
Director, Global Regulatory Affairs
7000 Portage Road Unit 0638-298-106
Kalamazoo, MI 49001

Dear Dr. Tripathi:

Please refer to your new drug application (NDA) dated December 22, 2000, received December 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Somavert (pegvisomant for injection) 10, 15, and 20 mg.

We acknowledge receipt of your submissions dated June 25, July 2, 3 (2), and 12, August 16 and 17, and November 2 and 5, 2001; January 14, April 30, May 31, August 28 and 29, September 12, 23, and 27, October 1, 7, 9, 11, and 28, November 4, 15, and 26, and December 19, 2002; and February 3, 10, and 13, and March 3, 7, 10, 24, and 25, 2003.

Your September 27, 2002, submission constituted a complete response to our June 26, 2001, action letter.

This new drug application provides for the use of Somavert (pegvisomant for injection) for the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (package insert submitted March 24, 2003 [enclosed], patient package insert submitted March 25, 2003 [enclosed], immediate container labels [pegvisomant vials and diluent vial] submitted March 24, 2003 [enclosed] and carton labels submitted March 24, 2003 [enclosed]). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you of your postmarketing study commitment to conduct a standard carcinogenicity study in a single species as specified in your submissions dated August 29, 2002, and March 10, 2003. Your commitment includes the following schedule:

Draft Protocol Submission:	June 2003
Study Start:	September 2003
Study Completion:	September 2005
Final Report Submission:	November 2006

Submit the protocol and study final report to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates and any changes in plans since the last annual report. All submissions, including supplements, relating to your postmarketing study commitment should be prominently labeled "**Postmarketing Study Protocol," "Postmarketing Study Final Report," or "Postmarketing Study Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We further remind you of the following chemistry, manufacturing, and controls agreements confirmed in your March 7 and 10, 2003, submissions. Report the status of these agreements in your annual reports according to 21 CFR 314.81(b)(2)(viii).

1. To develop and implement a(b)(4)-------- assay for the drug substance and drug product within one year of approval.
2. To validate the specified drug substance(b)(4)method and implement a specification by June 30, 2003.
3. Within six months of approval of Somavert, to submit a revised diluent label that replaces the phrase "Do not give intravenously unless rendered nearly isotonic" with the phrase "For drug diluent use with Somavert."

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 Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, MD
Director
Office of New Drug Evaluation II
Center for Drug Evaluation Research

Enclosures: Package Insert
Patient Package Insert
Pegvisomant Container (vial) Labels (3)
Carton Labels (3)
Diluent Container Label

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer

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