DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-931/S-028

Pharmacia & Upjohn Company
Attention: Shelley Beadle
Global Regulatory Director
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Beadle:

Please refer to your supplemental new drug application dated February 11, 2003, received February 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for R-Gene® 10 (10% arginine hydrocloride injection, USP).

This supplemental new drug application provides for a revision of the package insert to add a Geriatric Use subsection to comply with 21 CFR § 201.57(f)(10).

We completed our review of this application. 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 enclosed labeling (package insert submitted February 11, 2003).

Please submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – NDAs." 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-931/S-028." Approval of this submission by FDA is not required before the labeling is used.

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, 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

ENCLOSURE

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

/s/

Enid Galliers

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