DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-379/S-017
NDA 20-755/S-005
NDA 21-212/S-002

Pharmacia & Upjohn Company
Attention: John S. Walker
Senior Regulatory Affairs Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Walker:

Please refer to your supplemental new drug applications dated December 30, 2002, received December 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Caverject® Sterile Powder, Caverject® Injection (alprostadil injection) aqueous, and Caverject Impulse™ (alprostadil for injection).

These supplemental new drug applications provide for revised package inserts, in compliance with 21 CFR 201.57(f)(10), regarding the addition of a Geriatric Use subsection to the labeling.

We completed our review of these applications, as amended. These applications are 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 package insert submitted December 30, 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-379/S-017, NDA 20-755/S-005, and NDA 21-212/S-002." Approval of these submissions 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 Charlene Williamson, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
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/

Daniel A. Shames

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