CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-755

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-755

OCT 31 1997

Pharmacia & Upjohn, Inc.
Attention: Mr. Greg Shawaryn
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Shawaryn:

Please refer to your new drug application dated July 26, 1996, received August 2, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Caverject Injection (alprostadil injection) aqueous.

We acknowledge receipt of your submissions dated November 19 and 22 and December 6, 1996, and April 21 and 25, July 23 and October 6, 23, 24, 30 and 31, 1997. The original User Fee goal date for this application was August 2, 1997. Your submission of July 23, 1997 extended the User Fee goal date to November 2, 1997.

This new drug application provides for an aqueous formulation for the treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology. In addition, intracavernosal Caverject is indicated as an adjunct to other diagnostic tests in the diagnosis of erectile dysfunction.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated October 23 (carton and container) and October 30 (package insert), 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on October 23 (carton and container labels) and October 30 (package insert), 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 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 "FINAL PRINTED LABELING" for approved NDA 20-755. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitment to submit the results

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We further remind you of your intent to add a Clinical Studies subsection to the labeling post approval in the form of a supplemental application to this NDA.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, please contact Terri F. Rumble, B.S.N., Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products (HFD-580)
Office of Drug Evaluation II
Center for Drug Evaluation and Research