DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

APR 28 1997

**TRANSMITTED VIA FACSIMILE**

Kathleen J. Day
Director, Labeling and Promotion
Pharmacia and Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

**RE: NDA# 20-379**
Caverject (alprostadil for injection)
MACMIS ID #5277

Dear Ms. Day:

Reference is made to Pharmacia and Upjohn Company's February 7, 1997, FDA Form 2253 submission consisting of a User letter (USD6962), a User Guide (USX6961), and a price sheet (USX7141) for Caverject (alprostadil for injection). The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these materials and finds the User Guide (USX6961) to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations. Specifically, DDMAC has identified the following violations:

1. The last question and answer appearing on page 15 is misleading because it implies that Caverject may be used for "up to a week after mixing...." This is contrary to the approved product labeling for Caverject, which states "After reconstitution, the solution of Caverject should be used immediately and not stored or frozen."

2. The User Guide is misleading because the safety information is not displayed with a prominence and readability comparable to information on effectiveness. The bolded information at the bottom of page 15 appears to be the end of the piece, thereby discouraging patients from reading further and learning about safety information presented on the last page. Further, unlike the other sections, the safety information page does not have its own colored page stripe.

DDMAC recommends that Pharmacia and Upjohn immediately discontinue the use of this, and all other promotional materials for Caverject that contain the same or similar violations. Please respond to these comments in writing by May 9, 1997. This response should include a list of all similarly violative promotional materials and Pharmacia and Upjohn's method for discontinuing their use.

If Pharmacia and Upjohn has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Pharmacia and Upjohn that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID # 5277 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising, and Communications

File Name: apr23nov.let

Revised: Askine Date: 04/23/97
Comment: O'Brien Date: 04/23/97
Concur: O'Brien Date: 04/29/97

CC:
HFD-40/NDA # 20-379
HFD-40/Chron/Askine/Palmer
HFD-580/NDA 20-379

MACMIS ID # 5277

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 49292 Material ID#: USX6961.00

Due Date: May 9, 1997
Close Out: NO

FOI Status: Releasable