DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JAN 23 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 #5041

Dear Ms. Day:

Reference is made to Pharmacia and Upjohn's December 31, 1996, FDA Form 2253 submissions consisting of eight journal advertisements and a business reply card for Caverject (alprostadil for injection). The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed theses materials and find them to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations. Specifically, DDMAC has identified the following violations:

- **Placement and size of proprietary and established name**

Pursuant to the regulations, the established (generic) name is required to be placed in direct conjunction with the proprietary (brand) name in promotional labeling and advertising. However, DDMAC notes that the established name does not appear with the proprietary name at the first and most prominent mention of the proprietary name in each of these advertisements. Further, DDMAC finds that the established name is absent on the business reply card.

DDMAC recommends that Pharmacia and Upjohn immediately discontinue the use of these, and all other promotional materials for Caverject that contain the same or similar violations. Please respond to these comments in writing by February 3, 1997. This response should include a list of all 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 # 5041, in addition to the NDA number.

Sincerely,

Mark W. Askine

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

File Name:cjectnov.let

Drafted:	Askine	Date: 01/21/97
Comment:	Fleischer	Date: 01/21/97
Revised:	Askine	Date: 01/21/97
Concur:	Drezin	Date: 01/22/97

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

MACMIS ID # 5041

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 47950 Material ID#: All ID #'s listed

Due Date: February 3, 1997
Close Out: NO

FOI Status: Releasable