DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTED VIA FACSIMILE

NOV 25 1998

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

RE: NDA# 20-379
Caverject (alprostadil for injection)
MACMIS ID #7308

Dear Ms. Day:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Caverject (alprostadil for injection), disseminated by Pharmacia & Upjohn (P&U), that are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations. DDMAC specifically refers to a direct-to-consumer (DTC) journal advertisement that appeared in the November 8, 1998, issue of *Parade* magazine and P&U's October 29, 1998 submission of promotional exhibit panels on Form FDA 2253 that contain the following violations:

DTC Magazine Ad

Omission of Material Facts

The ad is misleading because it omits material facts in light of the representations made about Caverject. Specifically, the fact that Caverject is a prescription medication that must be injected via a needle that is inserted directly into the penis is not disclosed. It is also not disclosed that Caverject should not be used more than three times per week, with at least 24 hours between each dose. This information is needed to provide context to the claim "...Caverject can help you and your partner enjoy renewed spontaneity...."

Lack of Fair Balance

The ad is misleading because it fails to disclose important contraindications and other risks associated with Caverject therapy. For example, the advertisement does not disclose, in

understandable language, that Caverject is contraindicated in patients with conditions that might predispose them to priapism, such as sickle cell anemia or trait, multiple myeloma or leukemia, or in patients with anatomical deformation of the penis. The ad also fails to disclose, in understandable language, that penile fibrosis, including Peyronie's disease, was reported in clinical studies with Caverject. Finally, the ad minimizes the potential severity of priapism (erection lasting over 6 hours), which can cause serious and permanent damage to the penis (emphasis added).

Exhibition Panels

Unsubstantiated Comparative Claim

"Given a choice, what man wouldn't first choose a pill to treat his erectile dysfunction. Given an inadequate response, what man wouldn't then want the efficacy and reliability of CAVERJECT?"

This claim is misleading because it suggests than Caverject is more effective than oral medication in treating erectile dysfunction without substantial supporting evidence. The claim also suggests that Caverject will be effective in men who are unresponsive to oral medication, a claim that is also unsupported.

Fair Balance

Promotional materials may be false, lacking in fair balance, or otherwise misleading if they fail to present the information relating to side effects and contraindications of the drug with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. The regulations state that all techniques likely to achieve emphasis be considered, including, but not limited to, factors such as typography, layout, contrast, headlines, paragraphing, and white space. DDMAC concludes from its review of P&U's exhibit panels that the panels fail to provide fair balance. There appears to be some risk and other contextual information associated with the use of Caverject presented at the bottom of one of the panels. However, because the information is presented in extremely small type size, it is virtually illegible.

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 December 10, 1998. This response should include a list of all similarly violative promotional materials and Pharmacia and Upjohn's method for discontinuing their use.

If Pharmacia & 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 P&U that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #7308 in addition to the NDA number.

Sincerely,

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