



Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAR 19 1998

Kathleen J. Day
Director
Regulatory Affairs
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

RE: **NDA# 20-246**
Depo-Provera Contraceptive Injection (sterile medroxyprogesterone acetate)
MACMIS ID# 6421

Dear Ms. Day:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of two direct-to-consumer (DTC) broadcast advertisements for Depo-Provera Contraceptive Injection (sterile medroxyprogesterone acetate) that are misleading, lacking fair balance, or otherwise in violation of the Federal Food, Drug, and Cosmetic Act (the Act). DDMAC refers to Pharmacia and Upjohn's (Upjohn) "Barbecue" and "Birthday" broadcast advertisements for Depo-Provera.

Specifically, both advertisements are misleading and lacking fair balance because the risk information disclosed as part of the required "major statement" is not presented in a manner comparable to that used to present the information relating to efficacy. The major statement information concerning the failure of Depo-Provera to protect against HIV infection and other sexually transmitted diseases is presented in the video part of the advertisements while a competing message about other risk information is being presented in the audio part of the advertisement. These competing messages, coming from different modalities, virtually ensure that consumers will have trouble fully comprehending any of the information.

Also, the established name in both advertisements fails to have prominence commensurate with the proprietary name because it is not large enough to be read under normal television viewing conditions. Thus, both advertisements are in violation of the Act.

Finally, in both advertisements, the disclosure relating to the component of the "adequate provision" procedure that should direct the viewer to their doctor or pharmacist for additional product information does not adequately accomplish this communication. The viewer is merely told to "ask your healthcare provider if Depo-Provera is right for you." This focus on whether the product is "right" for the patient undermines the purpose of this part of an "adequate provision" procedure, which is to let the consumer know that there is additional product information that they can get from different sources.

DDMAC requests that Upjohn immediately discontinue the use of the above broadcast advertisements and any other promotional materials that have similar violative issues. Upjohn should respond, in writing, with its intent to comply with DDMAC's request by April 2, 1998. This response should include a description of Upjohn's plan for addressing the issue.

If you have 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 you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to the MACMIS ID # 6421 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications