DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB - 2 2000

TRANSMITTED VIA FACSIMILE

Rita Wittich
Director, Regulatory Affairs
Pfizer Pharmaceuticals
235 East 42nd Street
New York, NY 10017-5755

RE: NDA 20-895
Viagra (sildenafil citrate) tablets
MACMIS ID #8693

Dear Ms. Wittich:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a direct-to-consumer (DTC) broadcast advertisement for Viagra (sildenafil citrate) tablets that is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations. This DTC broadcast advertisement, submitted to the Agency on Form FDA 2253, is entitled "Valentine's Day."

Your "Valentine's Day" broadcast advertisement for Viagra contains written and graphic representations and suggestions about Viagra, yet fails to include information relating to Viagra's major side effects and contraindications. In addition, in the absence of a brief summary, the advertisement fails to make adequate provision for disseminating the approved product labeling.

Broadcast advertisements for prescription drugs that include representations or suggestions relating to the advertised drug product must include information relating to the major side effects and contraindications of the advertised drug. In addition, unless adequate provision is made for disseminating the approved product labeling in connection with the broadcast presentation, such advertisements must contain a brief summary of all necessary information related to side effects and contraindications.

DDMAC requests that Pfizer immediately cease using this advertisement and all other promotional materials for Viagra that contain the same or similar presentations. Pfizer should submit a written response to DDMAC, on or before February 17, 2000, describing its intent to comply with the above. Your written response should include a list of promotional materials that were discontinued, and the discontinuation date.

Pfizer should direct its response to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Pfizer that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #8693 in addition to the NDA number.

Sincerely,

/S/

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