



TRANSMITTED BY FACSIMILE

Robert B. Clark
Vice President, US Regulatory
Pfizer Inc.
Regulatory Affairs
235 East 42nd Street
New York, New York 10017

RE: NDA # 20-895
Viagra[®] (sildenafil citrate) Tablets
MACMIS ID # 12726

Dear Mr. Clark:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed two direct-to-consumer television advertisements (TV ads) for Viagra[®] (sildenafil citrate) Tablets (Viagra) submitted by Pfizer Inc. (Pfizer) under cover of Form FDA 2253 (ID# VG214424 and VG214415). The TV ads fail to disclose the drug's indication, fail to include information relating to the major side effects and contraindications, and fail to make adequate provision for dissemination of the FDA-approved or permitted package labeling, as required by 21 C.F.R. 202.1(e)(1) & (3). Moreover, the TV ads contain representations or suggestions that Viagra is better, more effective, or useful in a broader range of patients than has been demonstrated by substantial evidence or substantial clinical experience. See 21 C.F.R. 202.1(e)(6)(i). The TV ads thus misbrand Viagra in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(n).

Background

According to FDA-approved labeling (PI), "VIAGRA is indicated for the treatment of erectile dysfunction." The Contraindications section of the PI states, in part:

Consistent with its known effects on the nitric oxide/cGMP pathway (see **CLINICAL PHARMACOLOGY**), VIAGRA was shown to potentiate the hypotensive effects of nitrates, and its administration to patients who are using organic nitrates, either regularly and/or intermittently, in any form is therefore contraindicated.

The Warnings section of the PI states, in part:

There is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments for erectile dysfunction, including VIAGRA, should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.

Prolonged erection greater than 4 hours and priapism (painful erections greater than 6 hours in duration) have been reported infrequently since market approval of VIAGRA. In the event of an erection that persists longer than 4 hours, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result.

Additionally, the Precautions section of the PI includes the statement, “The use of VIAGRA offers no protection against sexually transmitted diseases.”

According to the Adverse Reactions section of the PI, Viagra is associated with headache, flushing, dyspepsia, and abnormal vision (defined as “mild and transient, predominantly color tinge to vision, but also increased sensitivity to light or blurred vision”).

Omission of Indication and Risk Information

The TV ads make representations about sexual activity in men who take Viagra. For example, the voiceover of the 30-second TV ad states (corresponding visuals in parentheses):

“Remember that guy who used to be called ‘Wild Thing?’” (Man watching wife examine high-heeled shoe in store)

“The guy who wanted to spend the entire honeymoon indoors?” (Man looking at high-heeled shoe in store)

“Remember the one who couldn’t resist a little mischief?” (Man gazing at black bra, panties, and negligee in store window)

“Yeah, that guy.” (Blue “horns” sprout from behind man’s head) (Trumpet blasts)

“He’s back.” (“He’s back.” written across man’s forehead) (Man moves and the horns become the “V” in Viagra)

“Viagra. Not all medications are for everyone.” (Man opening door to lingerie shop)

“Ask your doctor if Viagra is right for you.” (Man taking wife’s hand and leading her into shop)

The 15-second TV ad, which appears to be an abbreviated version of the 30-second TV ad, presents similar visuals with the voiceover “Remember that guy who used to be called ‘Wild Thing?’ Yeah, that guy. He’s back.” The TV ads thus make clear that Viagra is intended for sex.

The TV ads omit the indication for the drug (namely, treatment of erectile dysfunction) and fail to provide information relating to the major side effects and contraindications of the drug, as required by

21 C.F.R. 202.1(e). The TV ads also fail to make adequate provision for dissemination of the FDA-approved or permitted package labeling.

Unsubstantiated Effectiveness Claims

The TV ads claim that Viagra will provide a return to a previous level of sexual desire and activity. They refer to the sexually active past of the man (e.g., “Remember that guy who used to be called ‘Wild Thing’?”) and then declare “He’s back,” implying that, by taking Viagra, he has returned to that previous level of sexual desire and activity. FDA is not aware of substantial evidence or substantial clinical experience demonstrating this benefit for patients who take Viagra. If you have data substantiating this claim, please submit them to FDA for review.

Conclusion and Requested Actions

For the reasons discussed above, the TV ads misbrand Viagra under sections 502(n) of the Act, 21 U.S.C. 352(n).

DDMAC requests that Pfizer immediately cease the dissemination of promotional materials for Viagra the same as or similar to those described above. Please submit a written response to this letter on or before November 24, 2004, describing your intent to comply with this request, listing all promotional materials for Viagra the same as or similar to those described above, and explaining your plan for discontinuing use of such materials. Please direct your response to me at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 8B-45, 5600 Fishers Lane, Rockville, Maryland 20857, facsimile at (301) 594-6759. In all future correspondence regarding this matter, please refer to MACMIS ID # 12726 in addition to the NDA number. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Viagra comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Christine Hemler Smith, Pharm.D.
Consumer Promotion Analyst
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
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/s/

Christine Smith
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