



TRANSMITTED BY FACSIMILE

Jeffrey B. Kindler
Chairman and Chief Executive Officer
Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Re: NDA # 20-895
Viagra® (sildenafil citrate) Tablets
MACMIS ID # 16225

WARNING LETTER

Dear Mr. Kindler:

The Division of Drug Marketing, Advertising & Communications (DDMAC) of the U.S. Food and Drug Administration (FDA), through its routine monitoring and surveillance program, has reviewed a direct-to-consumer (DTC) promotional video (video) for Viagra® (sildenafil citrate) Tablets (Viagra) that appeared on www.cnn.com.¹ The video makes representations about the benefits of Viagra in the treatment of erectile dysfunction but fails to disclose any risk information associated with Viagra. Therefore, the video misbrands Viagra in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(a) & (n). The video raises public health and safety concerns through its complete omission of risk information for Viagra by suggesting that Viagra is safer than has been demonstrated.

Background

According to the INDICATION and USAGE section of the FDA-approved product labeling (PI), "VIAGRA is indicated for the treatment of erectile dysfunction." The PI also states that Viagra is associated with several important risks, including the following (in pertinent part) (original emphasis):

CONTRAINDICATIONS

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. . . .

¹ This video was viewed by DDMAC on [cnn.com](http://www.cnn.com) on March 16, 2008; it appeared as a commercial spot before a news video (<http://www.cnn.com/video/#/video/us/2008/03/15/vo.nyc.crane.collapse.wabc>). This video was also submitted by Pfizer under cover of Form FDA-2253 on March 19, 2008 (VGU00236B – Nashville spot).

WARNINGS

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....

PRECAUTIONS

Information for Patients

....Physicians should advise patients to stop use of all PDE5 inhibitors, including VIAGRA, and seek medical attention in the event of a sudden loss of vision in one or both eyes. Such an event may be a sign of non-arteritic anterior ischemic optic neuropathy (NAION), a cause of decreased vision including permanent loss of vision, that has been reported rarely post-marketing in temporal association with the use of all PDE5 inhibitors....

Physicians should advise patients to stop taking PDE5 inhibitors, including VIAGRA, and seek prompt medical attention in the event of sudden decrease or loss of hearing. These events, which may be accompanied by tinnitus and dizziness, have been reported in temporal association to the intake of PDE5 inhibitors, including VIAGRA....

The use of VIAGRA offers no protection against sexually transmitted diseases....

According to the Adverse Reactions section of the PI, Viagra is associated with headaches, 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 Risk Information

The video shows a group of men in a Nashville studio playing instruments and singing the following song:

- "Hey fellas, check this out... First time I saw her, she set my world...y'know she set my world to reeling and as the years go by, for this country guy...well, we never lost the feelin'. Well, this billy goat, I played my last note...can't wait...I can't wait to get home...Viva Viagra!"

The video then ends with an audio voiceover that states "Talk to your doctor about Viagra, America's most prescribed treatment for erectile dysfunction." This video is misleading because it makes

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representations and suggestions about the use of Viagra for erectile dysfunction, but fails to disclose any risk information for the drug. Prescription drug promotional pieces that make a claim, as this piece does, must contain risk information. See 21 CFR 202.1(e). We note that the video begins with the SUPER, "See the important safety information on this page;" however, the cnn.com webpage did not include any risk information for Viagra when this video was played. Similarly, the version of this video submitted by Pfizer, Inc. (Pfizer) on Form FDA-2253 failed to contain any risk information.

Conclusion and Requested Actions

For the reasons discussed above, the video misbrands Viagra in violation of the Act, 21 U.S.C. 352(a) & (n).

DDMAC asks Pfizer to immediately cease dissemination of violative promotional materials for Viagra that are the same as or similar to those described above. Please submit a written response to this letter on or before April 30, 2008, describing your intent to comply with this request, listing all promotional materials for Viagra that are the same as or similar to those described above, and explaining your plan for discontinuing use of such materials. Because the violations described above are serious, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials. Please direct your response to me at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, 5901-B Ammendale Road, Beltsville, MD 20705-1266, facsimile at (301) 847-8444. In all future correspondence regarding this matter, please refer to MACMIS ID # 16225 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. Failure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

{See appended electronic signature page}

Thomas Abrams, R.Ph., M.B.A.
Director
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Thomas Abrams
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