#1454

VIAGRA

Public Citizen

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

August 27, 1998

Dr. David Jefferys
Director, Licensing Division
Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
UK
FAX: 44-171-273-0493

Dear Dr. Jefferys:

Public Citizen's Health Research Group is writing to urge the Medicines Control Agency to require important warnings on the labeling of the drug sildenafil (Viagra) that have been omitted from the drug's labeling in the United States. Public Citizen has petitioned the United States Food and Drug Administration (FDA) on July 1, 1998 and again on August 20, 1998 to correct the dangerously deficient labeling of sildenafil in this country. These two petitions are attached for your reference.

Public Citizen's Health Research Group has been promoting research-based, system-wide changes in U.S. health care policy, as well as advocating for the appropriate prescribing and use of prescription drugs since 1972. We testify before Congress and petition the FDA on issues such as banning or relabeling of drugs and the misleading advertising of prescription and non-prescription drugs by their manufacturers. Our publications help consumers make informed decisions about the health care they receive and the drugs they are prescribed.

The basis for the two Public Citizen Viagra petitions are as follows:

- Men with diseases that would have excluded them from participating in pre-approval clinical trials are not excluded from taking sildenafil in the FDA-approved labeling for the drug. For example, men with uncontrolled diabetes or diabetic retinopathy, stroke or myocardial infarction within six months of starting treatment with Viagra, cardiac failure, and unstable angina were excluded from pre-approval clinical trials, but are not excluded from use of the drug or warned that the drug has not been tested in men with these conditions in the FDA-

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approved labeling.

- The use of sildenafil with nitrates is a absolute contraindication for the drug and is listed in the FDA-approved labeling. However, significant blood pressure lowering has been noted both in animals and in humans when sildenafil is used alone and with other drugs, but this is not mentioned in the FDA-approved labeling for the drug.

- Sildenafil's effects on vision are understated in the FDA-approved labeling. A single dose study not mentioned in the FDA-approved labeling found that in doses of 100 mg to 800 mg of the drug, visual disturbances were seen in about one-half the subjects receiving doses greater than 100 mg, and included difficulty seeing in dim light, color aberrations, and color tinges.

- Numerous drugs are known to cause sexual dysfunction. The FDA-approved labeling for sildenafil does not warn physicians or patients about the long list of drugs that can cause impotence or other forms of sexual dysfunction so that dosages and drugs could be adjusted in order to decrease the likelihood that sildenafil is being prescribed as a treatment for drug-induced sexual dysfunction that could be remedied without using sildenafil (the list of such drugs is included in our July 1 petition).

- The American College of Cardiology and the American Heart Association (ACC/AHA) has convened a joint task force to examine the use of sildenafil in patients at risk from the cardiovascular effects of sildenafil. In an interim report issued August 10, the ACC/AHA task force said:

  The cardiovascular effects of Viagra may be potentially hazardous for patients with certain medical profiles, and clinicians need to exercise caution when advising the following patients who are considering taking Viagra:

  - Patients with active coronary ischemia [decreased blood flow to the heart] who are not on nitrates;

  - Patients with congestive heart failure and borderline low blood pressure and borderline low volume status;

  - Patients on a complicated multi-drug, anti-hypertensive program; and

  - Patients on drugs (erythromycin, cimetidine) or who have conditions (e.g. liver or renal disease) that can prolong the half-life of Viagra.

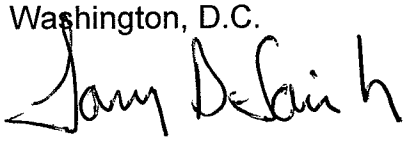
- None of the concerns of the ACC/AHA task force are reflected in the current

FDA-approved labeling for sildenafil other than the erythromycin and cimetidine drug interactions.

We strongly urge the Medicines Control Agency to ensure that the labeling for sildenafil includes important safety information that is missing from the U.S. labeling: (1) information from the statement of the ACC/AHA task force; (2) more information about the adverse effects of the drug on vision; (3) dangers of the drug's use with certain drugs for treating hypertension; and (4) contraindicated use of the drug in people with diseases or conditions which served as a basis for exclusion during pre-approval clinical trials. In addition, physicians and patients must be informed about the drugs that are known to cause sexual dysfunction in order to decrease the likelihood that sildenafil will be used as a treatment for drug-induced sexual dysfunction.

Sincerely,

Sidney M. Wolfe, M.D.
Director,
Public Citizen's Health Research Group
Washington, D.C.



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August 27, 1998

Professor M.D. Rawlins,
Chairman
Committee on Safety of Medicines
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1 Nine Elms Lane
London SW8 5NQ
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FAX: 44-171-273-0453

Dear Professor Rawlins:

Public Citizen's Health Research Group is writing to urge the Medicines Control Agency to require important warnings on the labeling of the drug sildenafil (Viagra) that have been omitted from the drug's labeling in the United States. Public Citizen has petitioned the United States Food and Drug Administration (FDA) on July 1, 1998 and again on August 20, 1998 to correct the dangerously deficient labeling of sildenafil in this country. These two petitions are attached for your reference.

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