



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 25 2005

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Jeffrey Klausner, M.D., MPH
STD Prevention and Control Service
1360 Mission Street
Suite 401
San Francisco, CA 94103

Docket No. 2004P-0351/CP1

Dear Dr. Klausner:

This letter responds to your citizen petition dated August 4, 2004, requesting that the Food and Drug Administration (FDA) change the labeling and other sources of information about Viagra (sildenafil) to address the association between its use and STD transmission, including HIV infection. In addition, you request FDA take steps to increase patient and physician awareness and education, to change the drug's marketing, and to classify Viagra as a controlled substance.

I am writing to inform you that we have not yet resolved the issues raised in your petition because it identifies significant matters requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0351

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