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2777 03 AUG -4 2003

August 2, 2004

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

To Whom It May Concern:

On behalf of the Board of Directors of the American Academy of HIV Medicine, I wish to lend my support to aspects of the citizen's petition submitted by Drs. Jeff Klausner, MD, MPH and Sean Swearingen from STD Prevention and Control Services, San Francisco Department of Public Health. Specifically, the Academy endorses the need for an alteration in the package inserts of all phosphodiesterase inhibitors to clearly and unequivocally state that there is an association between phosphodiesterase inhibitor use and sexually transmitted diseases, including HIV. Second, the Academy wishes that the package labeling be altered to state that it is the obligation of all prescribing physicians to probe patients for possible off-label use, particularly stimulant abuse. Third, we strongly endorse that all phosphodiesterase inhibitors should be used only under the direct clinical supervision of a prescribing physician. Accordingly, we believe that all Internet sales of prescription drugs should be stopped unless there is evidence of a direct and legitimate involvement of a licensed personal physician. Finally, we believe that the advertisement of prescription drugs and so-called "natural remedies" has gotten totally out of hand. The level of obfuscation and deception contained in this advertising to the public is truly frightening.

We at the Academy are dedicated to improving the excellence of HIV care to our patients. We believe that alteration in the labeling of phosphodiesterase inhibitors will aid our mission to achieve this goal.

Sincerely,

John D. Stansell, MD
Chair, Board of Directors
American Academy of HIV Medicine

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