Division of Dockets Management  
FDA  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852-0003  

Re: Citizens Petition to Compel Enforcement of Amyl Nitrite in re 21 CFR 250.100  
FDA Docket #2004P-0411/CP 1 filed September 9, 2004  

Dr. Lester Crawford, FDA Commissioner:  

Enclosed are supporting research articles and supporting declaration dated October 14, 2004. The enclosed articles are numbered to correspond with the reference listings. These submissions are in addition to previously submitted supporting documents #1-107.

Risk factor for unsafe sex:


Seroconversion risk factor


Immunosuppression risk factor


Prevalence of use


Overview articles showing why poppers use is hazardous and needs to be discouraged


Risk factor for Kaposi's Sarcoma

128. Drotman, Peter et al., Kaposi’s Sarcoma: How can epidemiology help find the cause? *JAMA* 13(3): 575-582.

**Example that is compelling because the sales ad endangers consumers:**

www.epoppers.com features both poppers and VIAGRA prominently in the website. Both poppers and VIAGRA are featured at the top of the website. Besides prominent location, the size and style of lettering are prominent and adjacent with NO CAUTIONARY warnings. This endangers consumers. This particular site selling poppers includes selling amyl nitrite poppers. FDA is aware of the lethal combination of poppers and VIAGRA. Action against these blatantly endangering websites is overdue.

Enforcement action in this blatant case seems obvious if FDA gives any value to protecting gay consumers. The impact of the AIDS epidemic effects everyone, because everyone pays for the costs of caring and dealing with morbidity in the AIDS epidemic. And it is in this AIDS epidemic context that we are petitioning for FDA to enforce the law and protect consumers.

...action, with penalties, will have both an education effect on unaware consumers and as well as a deterrent effect on those sellers who violate the laws. Both effects are desirable and can be achieved with minimal resources, but with wide ranging and long lasting impacts.

Enforcement action involves many options. FDA might start serving notice on violators. And publicize the giving of notice. Such publicity will serve as an alert to consumers. There is precedent for issuing alerts.

Sincerely,

Hank Wilson
Committee to Monitor Poppers/SURVIVE AIDS