

Committee to Monitor Poppers
1651 Market St. #303
San Francisco, CA 94103-1256
(415) 431-7476 Tel
henryruhe@aol.com

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852-0003
Telephone: 301-827-6860
Facsimile: 301-827-6870
E-mail: fdadockets@oc.fda.gov

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

Dr. Lester Crawford, FDA Commissioner:

The Committee to Monitor Poppers supports the Citizens Petition, Docket # 2004P-0411/CP 1 to compel FDA action against non prescription sellers of amyl nitrite.

Summary of rationale for supporting the petition:

Continued FDA nonenforcement of the prescription requirement of amyl nitrite sends a message to consumers that amyl nitrite is hazard free. Continued FDA inaction sends a message to doctors that amyl nitrite use is hazard free and requires no cautioning as would happen when doctors issue prescriptions. FDA inaction sends a message to potential sellers that there is no consequence in promoting and distributing non prescribed amyl nitrite. FDA inaction dismisses the accumulating research as if there was no public health impact of using poppers.

Enforcement is overdue. Research accumulates finding amyl nitrite immunosuppressive, and a significant risk factor in unsafe sex, hiv seroconversion, and Kaposi's Sarcoma. . Prevalence of use is high. The consuming community, both consumers and many doctors, is ignorant of the research, confused by mixed and/or changing messages overtime, and/or misinformed by deceptive advertising by the poppers industry.

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The public health impact is costly with every new amyl nitrite fueled HIV infection. Its not just the consumer that pays the price for using amyl nitrite, The public pays for the morbidity and costly care associated with each new hiv infection.

The public health impact justifies an expenditure of resources to enforce the prescription regulation. A time limited, ongoing, or even random publicized enforcement action will have a deterrent as well as education impact on both sellers, consumers, and doctors.

The consuming community needs an update and alert that research about the hazards of using amyl nitrite is accumulating. Doctors too need updating about the accumulating research on the hazards of abusing amyl nitrite. Both consumers and doctors initially focused on amyl nitrite use being a cause of AIDS. When HIV was discovered, the focus and concern about amyl nitrite/poppers use diminished or disappeared. Subsequent advertising by the poppers industry exonerated poppers use. A gourmet myth has currency among both consumers and doctors that amyl nitrite is "the safe one", the poppers formulation that is hazard free. The poppers industry ads foster this health endangering belief.

Some amyl nitrite sellers endanger consumers by promoting amyl nitrite and Viagra on the same website. There appears to be no consequence for advertising both poppers and Viagra despite them being a potentially lethal combination. A compelling reason for FDA to reassess its non enforcement of regulating amyl nitrite is the burgeoning sales and use of Viagra and non prescription sales of Viagra. Consumers need the prescription counseling about hazards of using amyl nitrite. Recreational Viagra use has emerged as a significant behavior among males, homosexual and straight.

Research:

1. Poppers use results in disinhibition(1) and research consistently finds poppers use a significant factor associated with unsafe sex (2-31) increasing the risk of acquiring HIV and other infections.
2. Studies of gay men in the United States found high rates of nitrite use (32-38).
3. Use of amyl nitrite results in immune suppression increasing susceptibility if exposed to HIV and other infections (39-73).
4. Research finds poppers use a significant risk factor for HIV infection. (74-84).
5. Amyl nitrite use has been associated with the transmission of KSHV (kaposi's sarcoma herpes virus) infection (85-89).
6. Amyl nitrite use has been found a cofactor for kaposi's sarcoma. (90-96) and promoter of angiogenesis (97).

Assumption: FDA Enforcement against the specified sites in the Citizen's Petition will have a deterrent effect on other sites currently selling amyl nitrite. Publicizing enforcement will deter new sites from offering amyl nitrite and it will deter other popper sites from adding amyl to menu of products.

Publicizing enforcement and sending notification of enforcement intent puts manufacturers, wholesalers, sellers on notice that they are breaking the law. Serving current notice lays the foundation for future consequential enforcement by FDA, Consumer Products Safety Commission, Department of Justice, Drug Enforcement Administration, etc. if there is non cooperation. It starts a paper trail insuring that violators cannot claim ignorance of the law. It increases the possibilities of larger fines and greater consequences if seller continue in violating the laws.

Recommendation: Any FDA enforcement actions should include education messages explaining to consumers the hazards in using amyl nitrite. The content would include the cautions a doctor might issue if prescribing amyl nitrite. If possible, FDA could issue mandates ordering corrective advertising about the hazards of using amyl nitrite and poppers. FDA should also educate violators about the documented research. The Committee to Monitor Poppers has been successful since our founding in 1981 in getting publications to stop advertising poppers. Our experience is that most sellers, like consumers and doctors, are unaware of the published research on the hazards of using amyl nitrite.

Education Effect: Enforcement will convey to consumers that using poppers and amyl nitrite can be hazardous. Failure to enforce conveys a message that use of amyl nitrite is hazard free. Our experience is that consumers assume that if there was harm, that FDA would intervene.

www.poppersexpress.com endangers consumers by referring them to the link www.allaboutpoppers.com which gives a green light to poppers use. That website promotes poppers use and Great Lakes Products specifically. It includes claims that poppers are as safe as aspirin. This sight uses deception in downplaying any hazards of using poppers. It distorts research and/or omits research finding that poppers are hazardous. It has over 500 links to other websites.

The specific sites sited in the Citizen Petition warrant FDA priority attention: FDA should consider several "magnifying harm" factors in prioritizing action against the specified sites. FDA should prioritize enforcement against these sellers because of their "Magnifying harm" impacts:

1. Prioritize action against selling sites that **sell both poppers and Viagra**. The combination of amyl nitrite and Viagra can be lethal. () www.nitroaroma.com warrants priority action because of the danger to consumers. In the case of www.nitroaroma.com the VIAGRA portion of the ad has prominent placement, top of site, large lettering. Deaths have already occurred when consumers have combined Viagra and poppers. West Hollywood 3 gay males in their 30s. As well as deaths in San Francisco and Boston.

2. Prioritize enforcement against sellers **distorting the hazards of using amyl nitrite/poppers**, including promotional product Faqs. This includes Any site referring consumers or linking customers to www.allaboutpoppers.com; or other sites which distort the hazards of using poppers. www.poppersexpress.com refers customers to www.allaboutpoppers.com
3. Prioritize enforcement against **sellers offering "AFFILIATE PROGRAM"** which enables or/and encourages new violators . www.vhcleaner.com has an "Affiliate Program" encouraging others to sell poppers.
4. Prioritize enforcement action against **any seller which uses "popper" or inhalant in its title, or product name, labelings or characterizations of product brands.** "Poppers" by definition are inhalants. Marketing of inhalants should not be tolerated prior to safety testing and FDA clearance. All the specified websites label somewhere on their sites their products as poppers or inhalants.

FDA should adopt some of the Federal Trade Commission policies on Deception in advertising. Especially evaluating a site in its totality of effect. Inclusion of Disclaimers do not undo overall effect. Content, prominence of placement all factors which dilute the effects of disclaimers. FTC has refused to deal with the false claims, misinformation, omissions in the popper websites. FTC refers complainants to FDA and Consumer Product Safety Commission. To date, there is no protection of the targeted consumers and targeted gay community in challenging deceptive websites.

Complete copies of specific referenced research citations can be furnished upon request.

Sincerely,

Hank Wilson
Committee to Monitor Poppers/SURVIVE AIDS

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c.c. via mail, facsimile or email:

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