

February 8, 2006

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket # 2004D-0555 Condoms and Nonoxynol-9

We, the undersigned submit these comments as a coalition of HIV/AIDS, public health and reproductive rights organizations especially concerned about the appropriate use of N-9. These comments pertain to the Class II Special Controls Guidance Document: *Labeling for Male Condoms Made of Natural Rubber Latex* issued on November 14, 2005.

Appropriately, the draft guidance for latex condoms with nonoxynol-9 (N-9) indicates that the extent of additional pregnancy protection provided by N-9 has not been measured, and that the N-9 lubricant does not protect against HIV/AIDS or other sexually transmitted diseases. Studies show that even at low doses, spermicides containing N-9 can cause massive, short-term damage to the rectal epithelium (lining), thereby increasing an individual's risk of contracting HIV and other STIs during anal intercourse.

Therefore, we would like to express our great concern that the FDA has not banned the production of condoms lubricated with the N-9. These condoms have not been proven to provide any additional protection against pregnancy and have been shown to potentially increase risk of contracting HIV if the condom is used rectally, thereby posing a significant health hazard.

However, if the FDA decides to take its current approach to labeling condoms with N-9, then the retail package and individual condom foil package should prominently warn consumers that—

- Frequent use (more than once a day) of the spermicide nonoxynol-9 (N-9) can irritate the vagina, which may increase the risk of getting HIV/AIDS from an infected partner.
- N-9 can damage the rectum and may increase the risk of getting HIV/AIDS from an infected partner. You should never use condoms with N-9 for anal sex.

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Because N-9, when used vaginally multiple times a day, can cause genital lesions and because of the proven danger of the use of N-9 condoms for anal intercourse, we strongly believe that this warning should appear more prominently on the retail package and on the individual condom foil package.

Thank you for your consideration of these comments.

Sincerely,

AIDS ACTION, Baltimore, MD
AIDS ACTION, Washington, DC
AIDS Coalition for Education
AIDS Foundation of Chicago
AIDS Project Los Angeles
AIDS Treatment Initiatives (ATI), Atlanta, GA
American Academy of HIV Medicine
American Medical Student Association (AMSA)
Catholics for a Free Choice
Champaign/Urbana Public Health District
Church Ladies for Choice
Churros-y-Chocolate
Florida Family AIDS Network
Center for Health and Gender Equity (CHANGE)
Global Campaign for Microbicides
Gutmacher Institute

Hyacinth AIDS Foundation
Internet Sexuality Information Services (ISIS, Inc.)
Los Angeles County HIV Drug & Alcohol Task Force
L.A. Gay & Lesbian Center
PATH
Pathfinder International
Planned Parenthood of Connecticut
Positive Living Program/TCN Behavioral Health
Services, Inc.
San Francisco AIDS Foundation
San Francisco Department of Public Health, STD
Prevention and Control Services
The AIDS Institute
The Center for Sex & Culture, San Francisco
The Woodhull Freedom Foundation
Treatment Action Group (TAG)