

UCHAPS ♦ *Urban Coalition for HIV/AIDS Prevention Services*

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

The Urban Coalition for HIV/AIDS Prevention Services (UCHAPS) is a coalition of community members and health departments from urban centers heavily impacted by HIV/AIDS. UCHAPS membership includes seven local jurisdictions directly funded by the Centers for Disease Control and Prevention (CDC) to conduct HIV prevention programs (Chicago, Houston, Los Angeles County, New York City, Philadelphia, San Francisco, and Washington D.C.). Collectively these cities represent more than one-third of the nation's AIDS cases and are among the epicenters of the urban HIV epidemic.

UCHAPS seeks to bring enhanced attention and resources to cities that have faced a disproportionate burden of infection throughout the history of the epidemic. The impact of HIV/AIDS in our cities has been compounded by the number of HIV infections among those citizens most disenfranchised from traditional systems of medical and health care. UCHAPS believes that by working together, members can enhance the federal and local responses to HIV and AIDS in urban environments.

The UCHAPS membership has reviewed the "Draft Guidance for Industry and FDA Staff-Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex" issued on November 14, 2005.

Our statements regarding Chapter VI. Labeling Recommendations (page 10), listed in this guidance are as follows:

A. Labeling Recommendations for Latex Condoms

2d. STDs transmissible by contact outside the area covered by a condom

The draft guidance tends to underestimate the effectiveness of condom use in preventing STIs that can be transmitted by contact with skin outside the area covered by a condom, including human papilloma virus (HPV) and herpes simplex. The statement recommendation, as listed, can be confusing to the average consumer.

"Important information: Condoms provide less protection for certain STDs, including genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. Condoms cannot protect against these STDs when they are spread in this way. Using latex condoms every time you have sex may still give you some benefits against these STDs. For example, using a condom may lower your risk of catching or spreading genital herpes. Using a condom also may lower your risk of developing HPV-related diseases, such as genital warts and cervical cancer. For more information consult your health care provider or information provided by government public health agencies.

The statement could read "The consistent use of male latex condoms can significantly reduce, but not eliminate, the risk of acquiring other STIs including, Syphilis, HPV and herpes simplex.

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Please consult your health care provider or your local government public health agencies for more information."

B. Labeling Recommendations Related to the Use of N-9 in Condoms with Spermicidal Lubricant

The membership believes that the draft guidance for latex condoms is scientifically accurate in that Nonoxynol-9 lubricant has had little to no proven protection from pregnancy, does not protect against HIV/AIDS or other sexually transmitted infections, and that N-9 has risks of vaginal irritation that could lead to increased risk of transmission of HIV/AIDS from an infected partner.

The UCHAPS membership endorses the FDA draft guidance for the labeling of male condoms (with the addition of the above stated recommendations regarding the effectiveness of protection against HPV and herpes simplex).

We appreciate the opportunity to provide these comments, and look forward to your attention to these concerns as you develop scientifically accurate information that will enable consumers to make informed decisions about condom use and sexual health. Please feel free to contact either of us for further information or discussion.

Sincerely,

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