

February 7, 2006

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

Re: Docket No. 2004D-0555

To Whom It May Concern:

The Gay Men's Health Crisis (GMHC), a 25-year-old national, not-for-profit organization that serves over 10,000 people living with HIV/AIDS and thousands of people at risk of HIV infection in New York City. GMHC is pleased to submit comments regarding the Food and Drug Administration's (FDA's) draft guidance on latex condoms, both with and without nonoxynol-9 (N-9), entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex."

We wish to offer comments on the draft guidance for the labeling of male latex condoms with a focus on our concern that the addition of overly complex language may confuse consumers about the risks and benefits of condoms and may inadvertently lead to decreased condom use. Our comments are limited to two key areas of the labeling recommendations: male latex condoms containing N-9 and STDs transmissible by skin-to-skin contact.

#### **Labeling Recommendations Related to the Use of N-9 in Condoms with Spermicidal Lubricant**

The draft guidance for latex condoms with N-9 states correctly that the extent of additional pregnancy protection provided by N-9 has not been measured, and that the N-9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 STDs. Moreover, in 2002 the Centers for Disease Control and Prevention and the World Health Organization recommended that couples be informed that N-9, when used vaginally multiple times per day, can cause genital lesions—a condition that may increase a woman's risk of acquiring HIV. Finally, and of extreme importance, studies show that, even at low doses, N-9 can cause massive, short-term damage to the rectal epithelium (lining), thereby increasing an individual's risk of contracting HIV and other STDs during anal intercourse.

Because of this evidence, GMHC has lent its name to a campaign to caution the public about the appropriate use of N-9 and to encourage responsible behavior by industry. Led by the Global Campaign for Microbicides and endorsed by more than 85 scientists and public health organizations, the campaign calls on manufacturers to remove N-9 from condoms and lubricants, because the small amount of N-9 they contain is dangerous if used rectally and offers no demonstrated contraceptive benefit. While there has been progress on this front, we are disappointed that some companies continue to produce N-9 condoms.

In light of the FDA's decision to proceed with labeling of condoms with N-9, we agree that a warning statement addressing vaginal irritation, damage to the rectal lining, and HIV/AIDS transmission must appear on the retail package; however, we feel that the guidance language stating the risk posed by N-9 and that the definitive language used may dissuade potential users from utilizing condoms altogether, even if no other barrier method of contraception is available.

For example, the suggested labeling for anal sex is definitive in its conclusion that condoms containing N-9 should not be used. GMHC fears that such a strongly worded warning may lead potential users (and readers of the product labeling) to reject condom use altogether. Perhaps, the best way to remedy this situation is to include language that explains that use of an N-9 containing condom is significantly safer than not using a condom at all.

In addition, the warning on vaginal irritation should clarify that *frequent use* can increase vaginal irritation, and it should define that term. Adding “(more than once a day)” would make the guidance consistent with the proposed warning statement for over-the-counter vaginal spermicides containing N-9, proposed by the FDA on January 16, 2003 (Docket No. 80N-0280).

In summary, we recommend that the **retail package** include the following statements on N-9, and that these statements be grouped together. Proposed new language appears in **bold** and language to be deleted is ~~crossed out~~.

*“The lubricant on this condom contains ~~the spermicide~~ nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 **on this condom** has not been measured, **and N-9 alone does not protect against HIV/AIDS or other sexually transmitted diseases.**”*

***Nonoxynol-9 Warning:***

- ***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.***
- ***You should not use condoms with N-9 for anal sex. N-9 can damage the rectum and may increase the risk of getting HIV/AIDS from an infected partner. Condoms with N-9 should not be used for anal sex; however, if a condom containing N-9 is the only method available, using this condom is significantly safer than not using a condom at all.”***

**Labeling Recommendations related to STDs transmissible by skin-to-skin contact**

The FDA’s suggested statement on condom effectiveness against those STDs that also can be spread through skin-to-skin contact, is confusing. It is true that these STDs cannot be entirely prevented by condom use. The fundamental point, however, is that although condoms provide less protection against these STDs, they do afford *some* protection. Therefore, we recommend editing the proposed paragraph on STDs spread through skin-to-skin contact to simplify the statement on condom effectiveness against these STDs and clarify as follows:

*“Condoms provide less protection for certain STDs that can also be spread by contact with infected skin outside the area covered by the condom, **such as genital herpes and human papillomavirus (HPV) infection.** ~~Condoms cannot protect against these STDs when they are spread in this way. Still, using latex condoms every time you have sex may still gives you some benefits~~ **protection** 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.”~~*

We thank the FDA for this opportunity to offer our comments on the important issue of condom labeling.

Sincerely,

Ronald Johnson  
Gay Men’s Health Crisis, Associate Executive Director