



February 6, 2006  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket #2004N-0556 Condom Labeling**

These comments address the November 14, 2005 *Class Two Special Controls Guidance Document: Labeling for Male Condoms Made of Rubber Latex*. Our points of concern regarding male condom labeling are following:

- 1) Regulations appropriately state that the effect of nonoxynol-9 (N-9) on preventing pregnancy and STDs with vaginal use has not been measured. Regulations also state that the use of N-9 in the rectum has been shown to cause massive, short term damage that may increase of HIV and STD transmission. Therefore, Lifelong AIDS Alliance recommends the message **“You should not use condoms with nonoxynol-9 for anal sex”** be displayed prominently, on the front of the box, for condoms with N-9.
- 2) Currently, labeling for condoms without nonoxynol-9 explicitly mentions STD transmission via the vagina and genital fluids, but does not explicitly include information about STD transmission via the rectum. Lifelong AIDS Alliance recommends that wherever vaginal and genital fluid STD transmission is mentioned, STD transmission via the rectum also be mentioned.
- 3) Because many people may not take time to read the fine print in condoms labeling, they may unintentionally purchase and use boxes of condoms which do not protect against pregnancy, STDs and/or HIV. Lifelong AIDS Alliance also recommends that the FDA require that packaging between latex condoms, latex condoms with n-9, natural membrane condoms, and novelty condoms look **CLEARLY** different.
- 4) Lifelong AIDS Alliance recommends that condom insert packaging contain references to national and local programs that address pregnancy and HIV prevention in a comprehensive manner. Warning labels are often not enough to provide prevention education for those at highest risk for HIV.

Lifelong AIDS Alliance provides food, housing and health insurance to people living with HIV/AIDS in King County. Lifelong also provides prevention education and is a leader in local, regional and national advocacy for people living with HIV/AIDS. Over 85% of Lifelong AIDS Alliance's clients live on less than \$15,000 per year. With a \$14 million budget, Lifelong AIDS Alliance is the leading AIDS service organization in the Pacific Northwest and is recognized nationally for its innovative work.

Thank you for taking these comments into consideration,

Lifelong AIDS Alliance  
Seattle, WA