



February 13, 2006

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

Federal Register **Docket No. 2004D-0555**

To Whom It May Concern:

I appreciate the opportunity to provide comments on the “Draft Guidance for FDA Staff for Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex”, proposed by the Food and Drug Administration (FDA) in the *Federal Register* of November 14, 2005.

It is important for consumers to be able to make informed decisions about the condoms they consider to maintain health and wellness and to protect their health from infection, disease and pregnancy. However, the Guidance Document may confuse consumers regarding several issues.

The following is our request that the Agency provide greater consideration to product safety and effectiveness as well as clear labeling.

Section A-Labeling Recommendations for Latex Condoms:

Pregnancy: Consumers should be provided complete information of contraceptive effectiveness. In *Section VI “Labeling Recommendations, A.1., Pregnancy”*, the Agency recommends the use of the table “Guidance for Industry-Uniform Contraceptive Labeling (July 23, 1998)”. We feel this table should be modified to include “perfect use” data. Consumers select and use contraceptives with the intention of being “perfect users”. Providing perfect use data helps the consumer to select the appropriate contraceptive method. Moreover, the inclusion of said data will emphasize to consumers the importance of correct and consistent use of any device to attain the best results.

STD Protection: Consumers should be provided more accurate information on STD protection. *Section VI “Labeling Recommendations, A-2d., STDs transmissible by contact outside the covered condom.”* Condoms do provide some protection against the most dangerous types of HPV and some protection against herpes. I believe the recommended/acceptable statements should be modified 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.** 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.~~”*

Section B-Labeling Recommendations Relating to the Use of Nonoxynol-9 in Condoms:

Pregnancy: Based on a literature search, I believe that condoms lubricated with the spermicide nonoxynol-9 have never been part of a contraceptive effectiveness study that has demonstrated any contraceptive benefit of the adjunct spermicidal agent nonoxynol-9. While I understand that this Draft Guidance Document is a review of proposed labeling, we recommend that the FDA explicitly request all manufacturers to discontinue the sale of nonoxynol-9 lubricated condoms until data is available to support that condoms with nonoxynol-9 offer consumers improved contraceptive protection over condoms without nonoxynol-9. Without such data, the FDA and manufacturers misrepresent an unsubstantiated benefit from a product with known risks.

If the Agency will not take this important public health step, then we ask that the following recommendation on labeling be considered. The labeling recommendations provided in this Guidance Document should adequately inform the consumer that nonoxynol-9 lubricated condoms carry many risks and no proven benefit. It is based on the foregoing that we recommend label changes.

In *Section VI.B.1a.*, “*Limited Benefits of N-9*”, the example of an acceptable statement should be modified as follows:

“~~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 has not been measured. There is no evidence that condoms with N-9 are more effective than condoms without N-9 in preventing pregnancy and there are increased risks associated with the use of N-9. Condoms without N-9 are recommended by health professionals as extremely effective in the prevention of pregnancy and STDs.~~”

In *Section VI.B.2a-c.*, “*Risks of N-9*”, there is no mention of the increased risk of urinary tract infection associated with the use of condoms lubricated with N-9. We feel that an additional nonoxynol-9 warning should be included to alert consumers to this risk.

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We fully support the FDA's efforts to ensure that people receive medically accurate information about condoms. Clearly, the FDA has a public health responsibility to ensure that products are safe and effective, and labeling are easily understood, and reflect the best science available. We appreciate the opportunity to provide our comments.

Respectfully,

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