

**Ansell**

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February 10, 2006

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

Re: Docket No. 2004N-0556  
Agency: Food and Drug Administration, HHS  
RIN 0910-AF21

Dear Sir or Madam:

Ansell Healthcare Products LLC, a major manufacturer of condoms for the United States and international markets, submits these comments on the Proposed Rule to amend the classification regulations for condoms and condoms with spermicidal lubricant containing nonoxynol-9 to designate a special control for natural rubber latex condoms with and without spermicidal lubricant. Ansell concurs with the Agency that the draft guidance document entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex" as the special control is sufficient to provide a reasonable assurance of the safety and effectiveness of latex condoms with spermicidal lubricant containing N-9. However, we submit the following comments on FDA's labeling recommendations for condoms with respect to the scope of the warnings and specific language for your consideration.

A. Labeling Recommendations for Latex Condoms

**1 and 2. Pregnancy and Sexually Transmitted Diseases (STDs)**

FDA recommends a combined statement for the two principal intended uses of latex condom that should appear on the principal display panel, on the primary condom package (individual foil), and in the package insert under a heading "Important Information", as follows:

*"When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy, and the risk of catching or spreading HIV, the virus that causes AIDS."*

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Ansell proposes the following statement:

**“If used consistently and correctly, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy, HIV/AIDS, and other STDs.”**

- It is Ansell’s position that the above statement is scientifically and medically accurate, and it incorporates condom protection against the overall risk of STD transmission as supported by Table 1 – STDs and Usual Route(s) of Transmission published in the Federal Register/Vol. 70, No. 218 on November 14, 2005/Proposed Rules.
- Condom effectiveness against transmission of STDs is discussed in the package insert. Consumers are directed on the retail package to refer to the insert for additional information on STD protection.
- The shorter statement conveys intended uses accurately and allows more space on the primary condom package for other required labeling, i.e. lot number, expiration date, country of origin (if applicable), etc.

FDA recommends the package insert for latex condoms should include a table comparing pregnancy rates resulting from condom use to those resulting from other barrier contraceptive methods.

Ansell, as well as other condom manufacturers, have not included this type of table in condom labeling, although a similar one was recommended in previous draft condom labeling guidance.

- “Typical Use” rates are not based on scientifically valid data. “There are obvious errors in the table as it is based on Dr. Trussel’s chart which was published in the non-peer reviewed text Contraceptive Technology by Dr. Hatcher. Having said that, there will always be errors in any chart devised since there is not a single well-controlled comparative study of all methods of birth control.” (See attached literature review by independent toxicologist Robert J. Staab, Ph.D., DABT, RAC)
- The FDA recommended table does not include ideal or perfect use percentages. Therefore, “Typical Use” data are inappropriate given that consumers who purchase condoms desire to and intend to use the condoms consistently and correctly.

In Section 2b, FDA recommends the retail package contain the following statement:

*“Important information: There are many types of sexually transmitted diseases (STDs) and different ways of catching or spreading infection. A latex condom can reduce the risk of STD transmission to or from the penis. However, some STDs can also be spread by other types of sexual contact. For additional information on STD protection, please read the enclosed insert.”*

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Ansell proposes the following statement on the retail package:

**“Important information: There are many types of sexually transmitted diseases (STDs) and different ways of catching or spreading infection. A latex condom can reduce the risk of STD transmission. For additional information on STD protection, please read the enclosed insert.”**

- Remove “to or from the penis” in light of consumer sensitivity to labeling on packages purchased from mass market retail outlets.
- Remove “*However, some STDs can also be spread by other types of sexual contact.*” This message is repetitive in that it is already conveyed in the first sentence.
- The package insert is identified as containing additional information on STD protection and is more appropriate for addressing transmission of STDs that are spread to or from the penis, as well as some STDs spread by other types of sexual contact.

FDA suggests the statements for the package insert in sections 2a, 2c and 2d could be combined into one package insert statement that would address all the applicable identified risks of pregnancy and STDs, as follows:

*“Important information:*

*When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. Latex condoms can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.*

*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 on STDs, consult your health care provider or information provided by government public health agencies.”*

Ansell proposes the following combined statement for the package insert:

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**“Important information:**

**If used consistently and correctly, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy, HIV/AIDS, and other STDs. Latex condoms can also reduce the risk of other sexually transmitted diseases (STDs), such as chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.**

**Condoms provide less protection for those STDs spread by contact with infected skin outside the area covered by the condom, including genital herpes and human papillomavirus (HPV) infection. Condoms cannot protect against those 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 on STDs, consult your health care provider or information provided by government public health agencies.”**

- The above statement addresses all the applicable risks of pregnancy and STDs identified by FDA in sections 2a, 2b, 2c and 2d
- the first sentence in paragraph two above more clearly explains to the end user that condoms provide less protection against those STDs spread by contact with infected skin not covered by the condom and clarifies to the end user that condoms do provide effective protection against those STDs as long as the condom covers the infected skin area

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

In Section 1a and 1b, FDA recommends the following acceptable statements to appear on the retail package, primary condom package, and package insert:

*“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.”*

*“The nonoxynol-9 (N-9) lubricant on this condom does not protect against HIV/AIDS or other sexually transmitted diseases.”*

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Ansell proposes the following minor revisions to the above statements:

***“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 is not known.”***

***“The nonoxynol-9 (N-9) lubricant does not protect against HIV/AIDS or other sexually transmitted diseases.”***

- Stating that additional pregnancy protection provided by the N-9 “is not known” rather than “...has not been measured” may be less confusing to end users who are not familiar with what, if any, measurement criteria exist.

In Section 2a, FDA recommends the following risk statement prefaced by the words “Nonoxynol-9 Warning” to appear on the retail package and package insert:

***“Nonoxynol-9 Warning: The spermicide nonoxynol-9 (N-9) can irritate the vagina. This may increase the risk of getting HIV/AIDS from an infected partner.”***

In Section 2b, FDA recommends the following risk statement prefaced by the words “Nonoxynol-9 Warning” to appear on the retail package and package insert:

***“Nonoxynol-9 Warning: If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without nonoxynol-9 (N-9).***

It is Ansell’s position that both of the above FDA recommended warning statements are alarmist and unwarranted because:

- There are no studies linking N-9 condoms to vaginal irritation and increased transmission of HIV.
- The N-9 studies showing increased transmission of HIV involved different vehicles (gels and suppositories) as well as dramatically higher doses (50-150 mg vs. <32 mg) and frequency of use (up to 20 times a day) than is typical of N-9 condoms (3 times a week).
- Certain consumers may read these warnings out of context with statements elsewhere on the package/insert. This could result in the incorrect view that ALL condoms are suspect and thus should not be used, or that N-9 condoms do not provide barrier protection to STDs. WHO, CDC and others state categorically that N-9 condoms are clearly preferable than no condom at all.
- If these warnings do not accurately inform the consumer, then the likely decline in condom sales, with the consequent reduction of use by consumers, would be consequences that FDA does not intend.

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(Please see attached literature review and N-9 condom use assessment by independent toxicologist Robert J. Staab, Ph.D., DABT, RAC)

Ansell proposes the following alternative statement appear on the retail package and package insert:

**“Nonoxynol-9 spermicide is:**

- **For extra protection against pregnancy ONLY**
- **NOT for extra protection against AIDS and other STDs”**
  
- Clarifies intended use of spermicides for extra protection against pregnancy ONLY and removes inaccurate and alarmist language regarding N-9 on condoms.

In Section 2c, FDA recommends the following risk statement prefaced by the words “Nonoxynol-9 Warning” to appear on the retail package and package insert:

*“Nonoxynol-9 Warning: You should not use condoms with nonoxynol-9 (N-9) for anal sex. N-9 can irritate the rectum and may increase the risk of getting HIV/AIDS from an infected partner.”*

Ansell supports the intended purpose of the above warning statement to appear on the package insert. However, Ansell proposes that the retail package carry an alternative caution statement as follows:

**“CAUTION: Spermicidal Lubricants Are For Extra Protection Against Pregnancy. Spermicidal Lubricants Are Not For Rectal Use.”**

- The above caution statement clearly identifies to the end user that the purpose of the spermicidal lubricant is for extra protection against pregnancy only.
- The caution statement also provides concise instruction to the end user that spermicidal lubricants are not for rectal use.
- The caution statement, combined with the alternative statement previously recommended above, **“Nonoxynol-9 spermicide is: - For extra protection against pregnancy ONLY - NOT for extra protection against AIDS and other STDs”** clearly provides information to the consumer on the retail package that N-9 does not decrease the risk of becoming infected with HIV and other STDs.

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Again, we appreciate the opportunity to submit our comments and suggestions. If you have any questions or need additional clarification, please call me at 334-615-2563 or e-mail to [cingram@ansell.com](mailto:cingram@ansell.com).

Respectfully,



Cynthia A. Ingram  
Regulatory Affairs Manager, Americas

Attachment