



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 28 2000

Richard Morey  
Kleinfeld Kaplan and Becker  
1140 Nineteenth St., N.W.  
Washington, D. C. 20036-6601

Re: Docket #99P-2852/CP 1

Dear Mr. Morey:

This is in response to your petition dated August 19, 1999, filed on behalf of Ansell Healthcare, Inc., requesting a variance from the statement required to appear on the individual packages of spermicidally lubricated condoms [47 FR 49022]. You propose a shorter statement that you believe will provide the essential information about spermicidal lubricants, and will improve readability of this statement as well as other information currently required to appear on condom labeling. The alternative statement you propose is as follows:

"This condom contains a spermicide, Nonoxynol-9, which can reduce the number of active sperm if semen spill outside the condom, although the decreased pregnancy risk is not known. For maximum effectiveness, this condom should be used with a vaginal spermicide."

As you indicated in your petition, this statement is very similar to one proposed in another citizen's petition, Docket 98P-0109, which was subsequently approved by the agency. Your proposed statement differs from the approved statement in that it omits a quantitative reference concerning the extent of decreased pregnancy risk. Readers could infer that the product does not reduce the risk of pregnancy. The agency believes that a quantitative reference, such as "extent" or "amount," is an important concept that needs to be included in the text.

The agency, therefore, is granting Ansell Healthcare's request to allow the proposed alternate statement provided that the statement includes a quantitative reference concerning decreased risk of pregnancy.

If you would like additional information regarding this matter, please contact John Farnham in our Office of Compliance at (301) 594-4616.

Sincerely yours,

Linda S. Kahan  
Deputy Director for Policy and Regulations  
Center for Devices and Radiological Health

99P-2852

PAY