

TAB 6

DRAFT

ATTACHMENT

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DIVISION OF REPRODUCTIVE ADDOMINAL, EAR, NOSE AND THROAT,
AND RADIOLOGICAL DEVICES
OFFICE OF DEVICE EVALUATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

INFORMATION FOR CONDOMS WITH A SPERMICIDAL LUBRICANT 510(k) SUBMISSION
FOR OBSTETRICS-CYNEGOLOGY DEVICES BRANCH

Please be advised that FDA reclassified the generic class condom with spermicidal lubricant from Class III (Premarket approval) into Class II (Special Controls) by order dated, August 9, 1982. [Docket Number 81P-0306; Schmid Laboratories, Inc., Condom with Spermicidal Lubricant]. This device is identified at 21 CFR Section 884.5310 as a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol-9. The condom is used for contraception and prophylactic purposes (preventing transmission of venereal disease). (47 FR 49022, October 29, 1982). This device is a Class II device with Panel/procode designation: 85 LTZ. As part of the reclassification of the condom with a spermicidal lubricant the minimum amount of spermicide has been established as 25 mg added to the condom prior to packaging.

For a condom that is to be lubricated with a spermicidal lubricant the following additional elements must also be addressed.

1. Provide the chemical composition of the lubricant base of the spermicidal lubricant and provide the concentration of the active ingredient (not less than 25 mg.) and the volume of the lubricant base/active ingredient to be applied to the condoms.
2. Please be advised the labeling (retail package) shall bear the expiration date of the spermicidal agent. Therefore, identify the proposed shelf life of the spermicidal agent and provide data to support the proposed expiration date. The data supporting the proposed expiration date of the spermicidal lubricant should include detailed protocols of testing procedures and quantitative data generated to assess the effect of the spermicidal lubricant on the integrity of the condom and determine the amount of available spermicide over time.
3. The condom with a spermicidal lubricant labeling must prominently and conspicuously bear, as defined in 21 CFR 801.60, a specific contraceptive effectiveness cautionary provision on the principal display panel of any package of the product and on any package insert included in the package of the product. Therefore, the following statement must be prominently displayed on the device labeling:

"This product combines a latex condom and a spermicidal lubricant. The spermicide, nonoxynol-9, reduces the number of active sperm, thereby decreasing the risk of pregnancy if you lose your erection before withdrawal and some semen spill outside the condom. However, the extent of decreased risk has not been established. This condom should not be used as a substitute for the combined use of a vaginal spermicide and a condom."