



**TO:** Interested Parties  
**FROM:** Reproductive Health Technologies Project  
**DATE:** December 3, 2008  
**RE:** Latex Condom Labeling FDA Final Rule Highlights

---

On November 10, 2008, the **Food and Drug Administration (FDA)** published a **final rule to amend the labeling of male latex condoms**. The rule establishes a “special control” for latex condoms; an FDA guidance document that identifies minimum performance standards, continued testing, and labeling recommendations for a device. Specifically, the FDA decided to issue this special control to address latex condom safety and effectiveness including FDA’s scientific conclusions on STI transmission risks with correct and consistent use.

Background:

The draft rule was first introduced in November 2005 and was particularly worrying because Senator Brownback (R-KS) was bent on undermining condoms as a method of STI and pregnancy prevention, not to mention FDA’s recent track record of putting ideology before science in the handling of other contraceptive methods. Fortunately, **RHTP believes the new rule is consistent with available scientific evidence and does not undermine current efforts to promote condoms as a means to reduce STI and unintended pregnancy rates.**

Key highlights and notes from the rule:

- **Science trumped ideology. FDA concluded that condoms reduce the transmission risk of ALL STIs they evaluated:** By analyzing systematic reviews and individual clinical studies, FDA stated that correct and consistent use of latex condoms reduces the risk of HIV/AIDS, gonorrhea, chlamydia, hepatitis B, genital herpes, HPV and syphilis. Of note is FDA’s support for including HPV as one of the STIs that condoms deter, a conclusion FDA did not make in 2005. They took into consideration new studies published after the release of 2005 draft rule and concluded that condoms reduce the prevalence of both HPV related diseases *and* the HPV infection itself.
- **Submitting comments facilitates change!** FDA received comments from advocates describing the proposed labeling as “misleading,” “overly complex,” and “possibly discouraging use.” To investigate these claims, FDA sponsored a latex condom label comprehension study. The results from this study showed that “the labeling contained in the draft guidance was too confusing for consumers, and did not effectively and adequately communicate the effectiveness of latex condoms against these ... STIs.” Based on this study, FDA shortened and simplified its recommended labeling.
- **This final rule reduced the scope of the proposed guidance:** Originally FDA looking at creating a special control for both condoms made of natural rubber latex (latex condoms) AND latex condoms with spermicidal lubricant containing nonoxynol-9 (N-9). They are still reviewing comments about condoms with spermicidal lubricant, so this guidance only pertains to latex condoms *without* N-9. We will stay on the lookout for a separate rule on N-9.