

Labeling for Male Condoms Made of Natural Rubber Latex
(Docket No. 2004N-0556 and RIN number 0910-AF21)

Comments from Family Health International (FHI)

After careful review, Family Health International (FHI) finds the FDA draft label for latex condoms to be scientifically based and accurate. FHI is a nonprofit international organization, managing research and field activities in more than 70 countries in the areas of HIV/AIDS and reproductive health.

In preparing the Barrier Chapter for the 4th edition of the well-respected text *Sexually Transmitted Diseases*, Drs. Steiner and Cates from FHI along with their colleagues Drs. Warner and Stone reviewed the most recent scientific evidence for the latex condom's effectiveness against HIV/STI and pregnancy. We drew similar conclusions to what the FDA is presenting in the current draft label.

Specifically, we write, "when used consistently and correctly, male latex condoms can reduce the risk of pregnancy and many sexually transmitted infections (STIs), including HIV. Strong evidence, based on biologic plausibility, laboratory studies and mounting data from clinical studies supports the public health recommendation that condom use reduces the risk of STI for sexually active persons." The 4th edition of *Sexually Transmitted Diseases* is forthcoming in the spring of 2006.

We are attaching three recent papers by FHI that make the following points relevant to the draft label:

- Simple labels communicate risk more effectively than more complicated ones (Steiner 2003).
- Clinical studies have shown latex condoms to be highly effective against sexually acquired HIV infection, the most serious STI. Thus, male latex condoms should be promoted to sexually active clients at risk for STI for this reason alone. (Cates 2001).
- Although far from perfect, the male latex condom is the most effective and least expensive prevention method for sexually active persons and increasing its use must remain the highest priority for any STD prevention program (Steiner 1999).