



MEMORANDUM

TO: Interested Parties
DATE: December 19, 2008
FROM: Reproductive Health Technologies Project
RE: FDA Panel Recommends Approval of the FC2 Female Condom

On December 11, 2008, the FDA's Obstetrics and Gynecology Devices Panel voted unanimously (15-0) to recommend approval of the second-generation female condom, FC2. The approval came after a full day of deliberation including oral comments from more than 12 women's and reproductive health advocates and written support garnered from over 170 advocates worldwide.

The panel's approval was made with the condition that the FC2 label must include language that specifies that FC2 was not tested for contraceptive or STI prevention in clinical trials but that FC2's contraceptive and STI prevention properties can be inferred from successful clinical trials with FC1, the first-generation female condom and from FC2 preclinical laboratory studies.

The major difference between FC1 and FC2 is the material of the sheath; FC1 is made of polyurethane and FC2 is made of nitrile, a material used in some male condoms. While price was not a factor in the panel's review, the manufacturing process for FC2 is less expensive than FC1 and agencies and individuals purchasing FC2 can expect lower costs, a point that many advocates raised for the panel.

Panelists commented that although the methodology used in the performance outcome study presented by the FC2 sponsor, the Female Health Company, was slightly flawed, the study was overall very strong and proved that FC2 was comparable to FC1, a key factor in the panel's approval. In their review, the FDA raised concerns about the inclusion of commercial sex workers in the study sample; however, several panelists confirmed that this was a strength of the study because it included a population that is likely to use the product.

The panel concluded that the benefits of FC2 far outweigh the risks. Panelists also added that public comments received from advocates helped bring to light the global need for the FC2 as a less expensive and more user-friendly female controlled method to help women protect themselves against STI's and unintended pregnancy.