



MEMORANDUM

TO: Interested Parties
DATE: March 13, 2009
FROM: Reproductive Health Technologies Project
RE: FDA Approves FC2 Female Condom

On March 11, 2009 the U.S. Food and Drug Administration (FDA) granted regulatory approval to the second-generation female condom, FC2. The approval came just three months after the FDA's Obstetrics and Gynecology Devices Panel voted unanimously (15-0) to recommend approval of FC2 in December 2008.

As the manufacturing process for FC2 is less expensive than its predecessor, FC1, the FDA approval means that individuals and agencies, including the U.S. Agency for International Development (USAID), can now purchase and distribute FC2 at significantly lower costs. This is an important factor in availability and access to FC2 for women and men worldwide, but especially in low-resource settings.



The female condom is the only method available that is intended for women-initiated prevention of both sexually-transmitted infections, including HIV, and unwanted pregnancies. The FDA's approval of FC2 is an important step in meeting the global need for methods that enable and empower a woman to take more control over her reproductive health.

While the timeline for the complete rollout of FC2 is unknown, the manufacturer of FC2, the Female Health Company (FHC), is gearing up to partner with other companies to speed up the process. Similarly, global women's health advocates are working to ensure a rapid response by U.S. government agencies in the procurement and distribution of the FC2 overseas.

For more information on FC2, please visit FHC's website: <http://www.femalehealth.com/>
FHC's press releases can be found here: <http://www.femalehealth.com/fhcoinvestor.html>