



FOR IMMEDIATE RELEASE

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CONTACT: Serra Sippel

+1 202.393.5930

Mobile: +1 202.631.8808

ssippel@genderhealth.org

PRESS RELEASE

U.S. Food and Drug Administration Approves New Female Condom

Center for Health and Gender Equity Applauds Expansion of HIV Prevention Options for Women and Men Worldwide

(Washington, D.C.)—Today, the U.S. Food and Drug Administration (FDA) granted regulatory approval to the FC2 female condom, a lower-cost, second generation product manufactured by the Female Health Company—a move widely praised by HIV/AIDS and women’s health and rights advocates globally.

“We join women around the world in applauding the FDA’s swift action to approve the FC2 female condom,” stated Serra Sippel, executive director of the Center for Health and Gender Equity. “The HIV pandemic among women requires increased investment in woman-centered prevention options, and FC2 approval is an important step forward in putting the power of prevention in women’s hands.”

The female condom is currently the only method available to prevent HIV infection and unintended pregnancy that is designed for women’s initiation. FDA approval of the FC2 is significant since the new product will sell for about 30% less than its predecessor, the FC1. Female condoms have been relatively expensive in many parts of the world, due to a constellation of factors including manufacturing costs, bulk purchasing, and government and donor investment. Reduction in manufacturing costs, therefore, is one of many important avenues for making the new female condom more affordable and accessible to women and men in the U.S. and internationally.

Advocates are now calling on the U.S. government to react quickly to ensure rapid expansion of female condom distribution and programming, and have support from U.S. law. In the reauthorization legislation for the President’s Emergency Plan for AIDS Relief (PEPFAR) in 2008, Congress explicitly mentioned female and male condoms, emphasizing the importance of increasing availability and access to these commodities and ensuring consistent and correct use as essential for HIV/AIDS prevention efforts.

“We praise Congress for including specific references to female condoms, as both male and female condoms are safe and effective HIV prevention tools that are available to women and men today. We now look to the next leader of the Office of the Global AIDS Coordinator to ensure that female condoms are truly available, accessible and well-programmed for women and men worldwide,” said Serra Sippel.

The United States Agency for International Development (USAID) plans to phase out procurement of the FC1 upon FDA approval of the FC2, according to *Saving Lives Now*, a report by the Center for Health and Gender Equity. This means that potentially more female condoms can be procured, distributed and programmed overseas due to lower costs.

“Female condoms are a vital tool for prevention, women’s empowerment and communication between partners, and in Zimbabwe, we greatly welcome this decision by the U.S. FDA,” said Edinah Masiyiwa, executive director of Women’s Action Group (WAG) - Zimbabwe. “Women and men alike benefit from the female condom, with regard to their health, happiness and pleasure.”

The FC2 has the same design, appearance and use as the FC1, but is made of a different material—a synthetic rubber called nitrile. The FC2 holds all the benefits of the FC1 and is comparable in safety and effectiveness. Despite their many benefits, female condoms account for only 0.2% of the world’s total condom supply and make up only 1.6% of U.S. international condom shipments. It is unclear how long it will take before the FC2 is distributed through U.S.-funded HIV prevention programs overseas.

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The Center for Health and Gender Equity (CHANGE) is a U.S.-based non-governmental organization that seeks to ensure that U.S. international policies and programs promote sexual and reproductive health and rights through effective, evidence-based approaches to prevention and treatment of critical reproductive and sexual health concerns, and through increased funding for critical international programs and institutions.

Center for Health and Gender Equity (CHANGE)
1317 F Street NW, Suite 400, Washington, D.C. USA
Tel: 1.202.393.5930 · Fax: 1.202.393.5937 · change@genderhealth.org
www.genderhealth.org · www.pepfarwatch.org · www.preventionnow.net