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FDA Approves Plan B® One-Step Emergency Contraception With Lowered OTC Age Restriction

*New product a step in the right direction for women's health;
serious barriers to emergency contraceptive access remain*

Washington, D.C. –Today the Food and Drug Administration (FDA) approved Teva Pharmaceuticals, Inc.'s Plan B® One-Step. This one-pill (levonorgestrel tablet, 1.5 mg) emergency contraceptive method will be available for over-the-counter (OTC) purchase by women 17 years and older with valid identification, while women 16 years and younger must first obtain a prescription before acquiring the product. The original two-pill Plan B's OTC access is restricted to women ages 18 years and older.

“Lowering the age restriction on over-the-counter emergency contraception is a step in the right direction. It gives more women easier and faster access to this back up birth control method,” said Jennifer Rogers, Acting Executive Director of the Reproductive Health Technologies Project (RHTP).

“It is disappointing, though, that while the scientific evidence shows emergency contraception is safe and effective for women of all ages, a prescription will still be required for women 16 years and younger,” continued Rogers. “Emergency contraception is more effective the sooner it is used. The requirement that women 16 and younger obtain a prescription for emergency contraception is a significant barrier to use of this time-sensitive treatment. Doctors’ offices are often closed on evenings and weekends – when women are most likely to experience a contraceptive failure.”

“This age restriction is the legacy of years of political manipulation surrounding the approval of Plan B. The FDA is still working to undo damage that the past administration created by placing ideology over science,” said Susan Wood, Ph.D., Research Professor at the School of Public Health and Health Services at The George Washington University, and RHTP board member.

Plan B One-Step consists of a one-pill regimen and is a change from the original Plan B, which directed consumers to take one pill as soon as possible but not later than 72 hours after unprotected sex and then a second tablet twelve hours later. “The option to take one pill instead of two gives women a more accessible, straightforward contraceptive. And that’s always important when it comes to helping a woman prevent unintended pregnancy,” said Rogers.

For more information, please visit: <http://www.rhtp.org>

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Jennifer Rogers, RHTP, and Susan Wood, Ph.D., Research Professor, School of Public Health and Health Services at The George Washington University, are available for interview upon request.