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Women’s Health Advocates Celebrate FDA Decision to Remove Restrictions on Generic Emergency Contraception

Generic Emergency Contraceptive Pills Move One Step Closer to Full Over-the-Counter Status

(WASHINGTON, DC) --- Late Tuesday, the U.S. Food and Drug Administration (FDA) released a letter ruling that generic versions of the levonorgestrel-based emergency contraceptive (EC) pill Plan B One-Step® can be sold on store shelves without restriction. Labels for the generics must indicate the product is intended for use only by women ages 17 and older, but women will not need to show proof of age in order to purchase it.

This means that in the very near future, people seeking generic emergency contraception, which tends to cost $7 less on average than the brand name product,¹ will be able to get it directly off the shelf instead of from a pharmacist. Moving generic products to the shelf will also hopefully result in market competition that will drive down the price of EC overall.

“This is a significant leap forward in obtaining full over-the-counter status for emergency contraception and we commend the FDA for this decision. EC can be used safely and effectively by people of all ages and it should be available without unnecessary and arbitrary barriers,” said Jessica Arons, President and CEO of Reproductive Health Technologies Project.

“We hope and expect that all manufacturers of generic EC products will submit applications with the suggested labeling to the FDA immediately. The sooner generic EC becomes available without point-of-sale restrictions, the sooner people will be able to purchase a more affordable, time-sensitive, back-up birth control option without delay.”

In making this move, the FDA will be in nearly full compliance with an April 5th, 2013 federal district court order requiring the FDA to “make [all] levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale or age restrictions.” Generic EC products will be able to drop the age limit in their labeling entirely when Teva, Plan B One-Step’s manufacturer, loses its market exclusivity for ages 16 and under on April 30, 2016.

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Jessica Arons, President & CEO of the Reproductive Health Technologies Project, is available for interview upon request.

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