



FDA Approves Generic Prescription Only Plan B® Emergency Contraception

On June 24th, 2009, the FDA approved Watson Laboratories Inc.'s generic version of Plan B® Emergency Contraceptive (EC). This generic drug was approved for **prescription-only** use in women ages 17 and under.

What exactly is a generic drug?

According to the FDA, "a generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."¹

Why was the Plan B generic approved for prescription-only usage, not over-the-counter (OTC) as well?

Duramed has marketing exclusivity for OTC Plan B for women 18 and over until August 24, 2009, thus the generic Plan B developed by Watson Laboratories Inc. could only be approved for prescription-only use at this time.

What is "marketing exclusivity"?

Marketing exclusivity means that the FDA has granted a competition-free period for a drug, often after the submission of new clinical studies. A generic drug cannot be marketed during this term specified by the FDA. When Plan B was approved for OTC use in August 2006, it was granted a 3-year market exclusivity period.

Why was the generic prescription-only Plan B approved for those 17 years and younger and not all women?

All generics must have the exact same labeling as the brand name drug. Currently, Plan B's prescription labeling says that it is "Rx only for age 17 and younger."

Does this mean that someone over the age of 18 with a prescription for Plan B could not receive the generic version of the drug?

The decision to allow women 18 and older who have been written a valid prescription to purchase the generic prescription version of Plan B will rest in the hands of pharmacists.

When should we expect to see this product in pharmacies?

Watson Laboratories Inc's prescription-only generic Plan B, also known as "Next Choice," is said to launch soon. We haven't been able to pin down an exact date.

What will this generic Plan B cost at the pharmacy?

As with brand-name drugs, the price of generic drugs can vary pharmacy by pharmacy. We can assume that the generic version of Plan B will cost less than its current branded price (generally \$35-60)². Most generic drugs cost 20 to 70 percent less than the brand-name equivalent³.

¹ <http://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismandDrugPreparedness/ucm134451.htm>

² <http://ec.princeton.edu/questions/eccost.html>

Why did the FDA approve the generic Plan B as prescription only for 17 year old women if the NY district court decided that EC was safe and effective for this age group?

Although we are pleased the NY District court ruled in our favor and that the FDA did not challenge this decision, the label change to allow over-the-counter access to 17 year old women can only be made at the request of Duramed Pharmaceuticals. We have not received any indication from Duramed or the FDA that this has been, or will be, done.

Does this approval mean a generic over-the-counter version of Plan B is imminent?

With a generic version already approved by the FDA for women 17 and younger, and the marketing exclusivity for Duramed to expire in August 24, 2009, we believe there is a great possibility that a generic Plan B will be available for over-the-counter use for women 18 and older. However, in order for this to happen, a pharmaceutical company must first submit an application to the FDA asking for approval to make generic Plan B available over-the-counter for women 18 and over.

This fact sheet hasn't answered my question. I'm still confused.

Please feel free to call or email Lydia Stuckey at 202-530-4401 or lstuckey@rhttp.org.

³<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/ucm116075.pdf>