

Morning After Pill To Be Available To Minors Without Prescription
News

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The U.S. Food and Drug Administration announced that it has approved an amended application submitted by Teva Women's Health, Inc. to market Plan B One-Step for use without a prescription by women 15 years of age and older.



After the FDA did not approve Teva's application to make Plan B One-Step available over-the-counter for all females of reproductive age in December 2011, the company submitted an amended application to make the product available for women 15 years of age and older without a prescription.

The product will now be labeled "not for sale to those under 15 years of age *proof of age required* not for sale where age cannot be verified." Plan B One-Step will be packaged with a product code prompting a cashier to request and verify the customer's age. A customer who cannot provide age verification will not be able to purchase the product. In addition, Teva has arranged to have a security tag placed on all product cartons to prevent theft.

In addition, Teva will make the product available in retail outlets with an onsite pharmacy, where it generally, will be available in the family planning or female health aisles. The product will be available for sale during the retailer's normal operating hours whether the pharmacy is open or not.

Plan B One-Step is an emergency contraceptive intended to reduce the possibility of pregnancy following unprotected sexual intercourse if another form of birth control (e.g., condom) was not used or failed. Plan B One-Step is a single-dose pill (1.5 mg tablet) that is most effective in decreasing the possibility of unwanted pregnancy if taken immediately or within 3 days after unprotected sexual intercourse.

Plan B One-Step will not stop a pregnancy when a woman is already pregnant, and there is no medical evidence that the product will harm a developing fetus.

Research has shown that access to emergency contraceptive products has the potential to further decrease the rate of unintended pregnancies in the United States, said FDA Commissioner Margaret A. Hamburg, M.D. "The data reviewed by the agency demonstrated that women 15 years of age and older were able to understand how Plan B One-Step works, how to use it properly, and that it does not prevent the transmission of a sexually transmitted disease."

The approval of Plan B One-Step for use without a prescription by women 15 years of age and older

is based on an actual use study and label comprehension data submitted by Teva showing that women age 15 and older understood that the product was not for routine use and would not protect them against sexually-transmitted diseases. These data also established that Plan B One-Step could be used properly within this age group without the intervention of a health care provider.

Because the product will not protect a woman from HIV or AIDS or other sexually-transmitted diseases, it is important that young women who are sexually active remember to see a health care provider for routine checkups. The health care provider should counsel the patient about, and if necessary test her for, sexually-transmitted diseases, discuss effective methods of routine birth control, and answer any other questions the patient may have.

Teva has indicated that it plans to educate consumers, pharmacy staff, and health care professionals about the product's new status. It has also indicated its willingness to conduct an audit of the age verification practices after the product is approved to ensure that the age limitation is being followed.

On April 5, 2013, a federal judge in New York ordered the FDA to grant a 2001 citizen's petition to the agency that sought to allow over-the-counter access to Plan B (a two dose levonorgestrel product) for women of all ages and/or make Plan B One-Step available without age or point of sale restrictions. However, Teva's application to market Plan B One-Step for women 15 and older was pending with the agency prior to the ruling.

The FDA's approval of Teva's current application for Plan B One-Step is independent of that litigation and this decision is not intended to address the judge's ruling.

The Department of Justice is considering next steps in the litigation. In the meantime, the FDA took independent action to approve the pending application on Plan B One-Step for use without a prescription by women 15 years of age or older.

There are currently three emergency contraceptive drugs marketed in the United States - Plan B One-Step, Plan B, and ella. Plan B, available from generic manufacturers, uses two doses of levonorgestrel (.75 mg in each tablet), taken 12 hours apart, and requires a prescription for women under the age of 17. Ella (ulipristal) is a prescription-only product that prevents pregnancy when taken orally within 120 hours (five days) after a contraceptive failure or unprotected sexual intercourse. The approval of Teva's application for Plan B One-Step does not affect the prescription status of these other drugs.