Statement from FDA Commissioner Margaret Hamburg, M.D. on Plan B One-Step

Bio-Medicine.Org

SILVER SPRING, Md., Dec. 7, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration (FDA) has been carefully evaluating for over a decade whether emergency contraceptives containing levonorgestrel, such as Plan B One-Step, are safe and effective for nonprescription use to reduce the chance of pregnancy after unprotected sexual intercourse.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

Plan B One-Step is a single-dose pill (1.5 mg levonorgestrel tablet) which is effective in decreasing the chance of pregnancy if taken within 3 days after unprotected sexual intercourse. The product contains higher levels of a hormone found in some types of daily use oral hormonal contraceptive pills and works in a similar way to birth control pills.

Plan B One-Step was originally approved in July 2009 for use without a prescription for females age 17 and older and as a prescription-only option for females younger than age 17. In February 2011, Teva Women's Health Inc. submitted a supplemental application seeking to remove the prescription-only status for females younger than age 17 and to make Plan B One-Step nonprescription for all females of child-bearing potential.

The Center for Drug Evaluation and Research (CDER) completed its review of the Plan B One-Step application and laid out its scientific determination. CDER carefully considered whether younger females were able to understand how to use Plan B One-Step. Based on the information submitted to the agency, CDER determined that the product was safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases. Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare pro
'/>"/>

SOURCE [2]

Source URL (retrieved on *05/06/2015 - 7:28am*):
http://www.mdtmag.com/news/2011/12/statement-fda-commissioner-margaret-hamburg-md-plan-b-one-step

Links:

[1] http://photos.prnewswire.com/prnh/20090824/FDALOGO
[2] http://www.bio-medicine.org/medicine-technology-1/Statement-from-FDA-Commissioner-Margaret-Hamburg--M-D--on-Plan-B-One-Step-22732-1/