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Media Inquiries: Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

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

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.

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 provider.

It is our responsibility at FDA to approve drugs that are safe and effective for their intended use based on the scientific evidence. The review process used by CDER to analyze the data applied a risk/benefit assessment consistent with its standard drug review process. Our decision-making reflects a body of scientific findings, input from external scientific advisory committees, and data contained in the application that included studies designed specifically to address the regulatory standards for nonprescription drugs. CDER experts, including obstetrician/gynecologists and pediatricians, reviewed the totality of the data and agreed that it met the regulatory standard for a nonprescription drug and that Plan B One-Step should be approved for all females of child-bearing potential.

I reviewed and thoughtfully considered the data, clinical information, and analysis provided by CDER, and I agree with the Center that there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential.

However, this morning I received a memorandum from the Secretary of Health and Human Services invoking her authority under the Federal Food, Drug, and Cosmetic Act to execute its provisions and stating that she does not agree with the Agency's decision to allow the marketing of Plan B One-Step nonprescription for all females of child-bearing potential. Because of her disagreement with FDA's determination, the Secretary has directed me to issue a complete response letter, which means that the supplement for nonprescription use in females under the age of 17 is not approved. Following Secretary Sebelius's direction, FDA sent the complete response letter to Teva today. Plan B One-Step will remain on the market and will remain available for all ages, but a prescription will continue to be required for females under the age of 17.

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