

HHS secretary overrules FDA on widening availability of Plan B drug

Levonorgestrel (Plan B One-Step, Teva Pharmaceuticals) will remain available by prescription only to adolescents aged 16 years and younger after the Health and Human Services (HHS) secretary overruled FDA's recommendation to allow the emergency contraceptive to be sold over the counter for this age group.

FDA Commissioner, Margaret Hamburg, MD, announced the agency's decision December 7 to approve the new drug application submitted by Teva Women's Health Inc., but noted that HHS Secretary Kathleen Sebelius had invoked her authority under the U.S. Federal Food, Drug, and Cosmetic Act to overrule the decision.

In her statement, Dr. Hamburg stressed that the thorough review process used by the Center for Drug Evaluation and Research (CDER) found the product was safe and effective in the younger age group, that the age group understood the product was for emergency purposes only, and that the product would not protect against sexually transmitted diseases, concluding this younger age group could use the product without healthcare provider intervention.

"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," Dr. Hamburg wrote in her statement.

However, Sebelius disagreed with FDA's conclusion stating her concern that the studies submitted did not include data on girls of all ages for whom the product would be available.

"It is commonly understood that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age, which I believe are relevant to making this determination as to non-prescription availability of this product for all ages," she said. Sebelius directed FDA to issue a complete response letter due to inadequate data to show that prescription dispensing should be eliminated for all ages.

Plan B One-Step is a 1.5-mg, single-dose tablet that can prevent the chance of pregnancy if taken within 72 hours of sexual intercourse. The drug has been available without a prescription to women aged 17 and older and as a prescription-only option since July 2009 for females aged 16 and younger. In February 2011, Teva Women's Health Inc. submitted a supplemental application for the drug to be made available nonprescription for all females of child-bearing potential.