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US denies bid to expand morning-after pill sales

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US regulators on Wednesday rejected a drug company's request to make emergency contraception available over the counter to consumers of all ages instead of by prescription to those under 17.

The rare move, which saw one government secretary overrule another at the 11th hour, was blasted by pro-choice advocates but hailed by conservatives who said girls 12-17 need to see a doctor before getting the morning-after pill.

At issue was a drug called Plan B One-Step, made by Pennsylvania-based Teva Pharmaceuticals which had petitioned the US Food and Drug Administration to make it available on drugstore shelves to anyone over 12.

The pill can reduce the chance of pregnancy if taken within 72 hours of unprotected sex. It is currently available by prescription only to people under 17 in the United States.

Those over 17 can ask for it at a pharmacy counter without a doctor's prescription.

An FDA division that monitors drugs and reviews new applications, the Center for Drug Evaluation and Research (CDER), supported wider access for the morning-after pill, according to FDA commissioner Margaret Hamburg.

CDER found "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," she said in a statement.

However, Health and Human Services Secretary Kathleen Sebelius disagreed with the FDA decision, and invoked her authority to block the supplement for non-prescription use for females under 17.

"It is common knowledge that there are significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age," Sebelius said in a statement.

"Because I do not believe enough data were presented to support the application to make Plan B One-Step available over the counter for all girls of reproductive age, I have directed FDA to issue a complete response letter denying the supplemental new drug application."

That meant the drug's status would remain unchanged -- available without a prescription to women 17 and older and by prescription only for younger girls.

"Secretary Kathleen Sebelius was right," said Jeanne Monahan, spokeswoman for the Family Research Council, a well-known conservative group in the United States.

"The availability of Plan B over-the-counter for all ages would have bypassed necessary routine medical care for sexually active girls," she said, citing the risk of STDs and sexual abuse.

"Finally, Plan B can act in a way that can destroy life by preventing implantation. Women of all ages have the right to know how this drug may act in their bodies and on their newly developing babies."

The pill contains 1.5 milligrams of levonorgestrel, a higher level of a hormone found in birth control pills.

Plan B One-Step was first approved in 2009 for use without a prescription in those aged 17 and over, but was available to younger girls with a doctor's prescription.

"We commend the FDA for making the recommendation to approve providing women with increased over-the-counter (OTC) access to Plan B One-Step," said a statement by Teva spokeswoman Denise Bradley.

"And we are disappointed that at this late date, the Department of Health and Human Services has come to a different conclusion."

Kirsten Moore, president of the Reproductive Health Technologies Project, an advocacy group that had supported drugstore shelf access for all ages, expressed anger at President Barack Obama's administration.

"We are outraged that this administration has let politics trump science. There is no rationale for this move. This is unprecedented as evidenced by the commissioner's own letter. Unbelievable," she said.

The National Organization for Women called the move "a stunning betrayal of women."