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FOOD AND DRUG ADMINISTRATION

Decision Process to Deny Initial Application for Over-the-Counter Marketing of the Emergency Contraceptive Drug Plan B Was Unusual

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Highlights

Highlights of GAO-06-109, a report to congressional requesters

Why GAO Did This Study

In April 2003, Women's Capital Corporation submitted an application to the Food and Drug Administration (FDA) requesting the marketing status of its emergency contraceptive pill (ECP), Plan B, be switched from prescription to over-the-counter (OTC). ECPs can be used to prevent an unintended pregnancy when contraception fails or after unprotected intercourse, including cases of sexual assault. In May 2004, the Acting Director for the Center for Drug Evaluation and Research (CDER) issued a "not-approvable" letter for the switch application, citing safety concerns about the use of Plan B in women under 16 years of age without the supervision of a health care practitioner. Because the not-approvable decision for the Plan B OTC switch application was contrary to the recommendations of FDA's joint advisory committee and FDA review staff, questions were raised about FDA's process for arriving at this decision. GAO was asked to examine (1) how the decision was made to not approve the switch of Plan B from prescription to OTC, (2) how the Plan B decision compares to the decisions for other proposed prescription-to-OTC switches from 1994 through 2004, and (3) whether there are age-related marketing restrictions for prescription Plan B and other prescription and OTC contraceptives. To conduct this review, GAO examined FDA's actions prior to the May 6, 2004, not-approvable letter for the initial application.

www.gao.gov/cgi-bin/getrpt?GAO-06-109.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

On May 6, 2004, the Acting Director of CDER rejected the recommendations of FDA's joint advisory committee and FDA review officials by signing the not-approvable letter for the Plan B switch application. While FDA followed its general procedures for considering the application, four aspects of FDA's review process were unusual. First, the directors of the offices that reviewed the application, who would normally have been responsible for signing the Plan B action letter, disagreed with the decision and did not sign the not-approvable letter for Plan B. The Director of the Office of New Drugs also disagreed and did not sign the letter. Second, FDA's high-level management was more involved in the review of Plan B than in those of other OTC switch applications. Third, there are conflicting accounts of whether the decision to not approve the application was made before the reviews were completed. Fourth, the rationale for the Acting Director's decision was novel and did not follow FDA's traditional practices. The Acting Director stated that he was concerned about the potential behavioral implications for younger adolescents of marketing Plan B OTC because of their level of cognitive development and that it was invalid to extrapolate data from older to younger adolescents. FDA review officials noted that the agency has not considered behavioral implications due to differences in cognitive development in prior OTC switch decisions and that the agency previously has considered it scientifically appropriate to extrapolate data from older to younger adolescents.

The Plan B decision was not typical of the other 67 proposed prescription-to-OTC switch decisions made by FDA from 1994 through 2004. The Plan B OTC switch application was the only one during this period that was not approved after the advisory committees recommended approval. The Plan B action letter was the only one signed by someone other than the officials who would normally sign the letter. Further, there are no age-related marketing restrictions for any prescription or OTC contraceptives that FDA has approved, and FDA has not required pediatric studies for them. FDA identified no issues that would require age-related restrictions in the review of the original prescription Plan B new drug application.

In its comments on a draft of this report, FDA disagreed with GAO's finding that high-level management was more involved with the Plan B OTC switch application than usual, with GAO's discussion about when the not-approvable decision was made, and with GAO's finding that the Acting Director of CDER's rationale for denying the application was novel. However, GAO found that high-level management's involvement for the Plan B decision was unusual for an OTC switch application and FDA officials gave GAO conflicting accounts about when they believed the decision was made. The Acting Director acknowledged to GAO that considering adolescents' cognitive development as a rationale for a not-approvable decision was unprecedented for an OTC application, and other FDA officials told GAO that the rationale differed from FDA's traditional practices.