

# Judge: Make morning-after pill available to 17-year-olds

## Ruling says FDA delayed approval

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NEW YORK — The Food and Drug Administration let politics cloud its judgment when it denied teen girls over-the-counter access to the Plan B morning-after pill, a federal judge said yesterday as he ordered the FDA to let 17-year-olds obtain the medication.

U.S. District Judge Edward Korman blasted the FDA's handling of the issue during the Bush administration, saying it had "repeatedly and unreasonably" delayed issuing a decision on the medication, marketed by Montvale, N.J.-based Barr Pharmaceuticals Inc. as Plan B.

Korman's ruling said the FDA in several instances had

delayed issuing a ruling for suspect reasons.

"These political considerations, delays, and implausible justifications for decision-making are not the only evidence of a lack of good faith and reasoned decision-making," he said. "Indeed, the record is clear that the FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use."

He said the FDA's denial of nonprescription access without age restriction went against the recommendation of a committee of experts it had created to advise it on Plan B.

Plan B reduces the chance of pregnancy if taken within three days after sex. It works by preventing ovulation or fertilization and interfering with im-

plantation of a fertilized egg, which some people consider the equivalent of abortion.

Korman ordered the FDA to permit Barr Pharmaceuticals, which was bought by Israel-based Teva Pharmaceutical Industries Ltd. late last year, to make Plan B available to 17-year-olds without a prescription under the same conditions as Plan B is now available to women older than 18. He said his order must be complied with within 30 days.

The ruling came in a lawsuit brought by individuals and groups seeking wider distribution and access to emergency contraceptives, as well as parents and their minor children seeking access. The suit was filed in 2005 by the Center for Reproductive Rights and others after the FDA denied a petition asking it to make Plan B available without prescription to women of all ages.