



### **Important Milestones in the History of FDA Approved Emergency Contraceptive Options:**

- September 1, 1998: Preven, containing progestin-only & ethinyl estradiol, becomes the first U.S Food and Drug Administration (FDA) approved emergency contraceptive product on the market.
- July 1999: FDA approves Plan B, a progestin-only emergency contraceptive pill, finding it safe and effective for women of all ages to use as a prescription product.
- February 2001: RHTP and the Center for Reproductive Rights, on behalf of more than 70 medical and public health organizations, file a Citizen's Petition with the U.S. Food and Drug Administration to make EC available over-the-counter.
- April 21, 2003: The manufacturer of Plan B files an application with the FDA to make it available over-the-counter.
- December 16, 2003: An FDA independent panel of experts votes 23 to 4 to recommend Plan B be made available over-the-counter, with no age restriction. The panel also votes unanimously that Plan B is safe for nonprescription use.
- May 2004: Preven is discontinued.
- May 6, 2004: Dr. Steven Galson, Acting Director of the Center for Drug Evaluation and Research, overrides FDA professional staff recommendations and issues a “not approvable” letter to Plan B’s manufacturer, citing concerns about young teens using the drug.
- July 22, 2004: Barr, the Plan B manufacturer, submits a revised over-the-counter proposal to FDA, which would make it available over-the-counter to women 16 and older while requiring a prescription for women 15 and under.
- January 21, 2005: FDA fails to issue a decision on the Plan B application by the deadline imposed under the federal law governing performance standards for drug approvals.
- March 17, 2005: Members of the Senate Committee on Health, Education, Labor, and Pensions (HELP) question FDA Acting Commissioner Lester Crawford about the agency’s inaction on the Plan B OTC application during hearings on his nomination to permanently head the FDA. Unsatisfied with Crawford’s answers, Sens. Clinton (D-NY), Murray (D-WA) and Kennedy (D-MA) request a closed-door meeting with him.
- April 6, 2005: Following the closed-door meeting, Sens. Clinton and Murray announce their intention to place a “hold” on Crawford’s nomination, citing the FDA’s failure to act on a host of public health issues—including the Plan B over-the-counter application—during Crawford’s tenure as acting commissioner.

- May 15, 2005: News reports indicate that David Hager, a controversial member of the FDA's Reproductive Health Drugs Advisory Committee, was asked to author an unprecedented minority opinion opposing FDA approval of over-the-counter access for Plan B — after the advisory panel voted overwhelmingly to support the application.
- July 15, 2005: Sens. Clinton and Murray lift the “hold” on Crawford's nomination to head the FDA after receiving assurances from Health and Human Services Secretary Mike Leavitt that the FDA will act on the Plan B over-the-counter application by September 1.
- August 26, 2005: Citing “regulatory and policy concerns” about whether Barr's ‘dual label’ proposal is permissible under FDA regulation, then-Commissioner Crawford announces his decision to submit the application to the administrative rulemaking process and open a 60-day public comment period on the application. This proposed rulemaking is a thinly veiled attempt to postpone the application indefinitely.
- August 31, 2005: Dr. Susan Wood resigns her position as Director of the Office of Women's Health and Assistant Commissioner for Women's Health at the FDA in protest over the FDA's handling of the Plan B application.
- September 13, 2005: The FDA announces that Dr. Norris Alderson, a senior official at the Center for Veterinary Medicine, has been appointed acting director to the Office of Women's Health. Three days later, the FDA announces Dr. Theresa Toigo, director of the Office of Special Health Issues, as the real acting director of the Office of Women's Health and denies Dr. Alderson's appointment.
- September 23, 2005: Citing age and personal issues, Crawford announces his sudden resignation as commissioner of the FDA. President Bush immediately appoints Dr. Andrew von Eschenbach, director of the National Cancer Institute, as acting commissioner.
- October 12, 2005: The Government Accountability Office (GAO) releases a draft report of the investigation into the FDA's denial of Barr's original application. The report deems the process leading up to the denial highly unusual, with an atypical level of involvement by high-ranking FDA officials. Further, the report shows there are conflicting accounts on when the decision was made.
- November 1, 2005: The period of time for public comments on the FDA Proposed New Rulemaking closes. The FDA does not reveal any plans on when it will move forward with the rulemaking process and it is not statutorily required to do so.
- February 16, 2006: Nearly a full 6 months after the FDA announced the Proposed New Rulemaking, Acting Commissioner von Eschenbach was called to testify before the House Agriculture Appropriations Subcommittee, where he faced intense questioning from Representatives Farr and DeLauro regarding the FDA's failure to act on the application or received comments. Dr. von Eschenbach did not provide any details of the FDA's schedule for Plan B.
- March 9, 2006: Representative Waxman, after receiving documentation that revealed that the FDA had, in fact, internally examined at least one year before the very issues it claimed were so “novel” as to require rulemaking, writes a letter to Dr. von Eschenbach. The letter asks why the FDA did not act in a timely manner on the information that it possessed, and also why the FDA deleted the e-mails of its senior staff in violation of the Federal Records Act. A response is requested by March 27, 2006.

- March 10, 2006: Dr. von Eschenbach is nominated by President Bush to become permanent director of the FDA 169 days after he was appointed as acting commissioner.
- Week of April 24, 2006: CRR carries out depositions of high ranking FDA officials with regards to bad faith in decision making on the Plan B application.
- July 31, 2006: The day before Dr. von Eschenbach's confirmation hearing begins, the FDA announces plans to meet with Barr to "to resolve the remaining policy issues" related to making Plan B available over-the-counter for women "18 years and older."
- August 1, 2006: During his confirmation hearing, Dr. von Eschenbach announces his support for Plan B to be available over-the-counter for women 18 years and older, but declines to offer any timetable.
- August 8, 2006: Barr meets with the FDA.
- August 18, 2006: The FDA announces that Barr has resubmitted its application to sell Plan B over-the-counter.
- August 21, 2006: In a press conference, President Bush indicates his support for Plan B for women 18 and older by saying, "I believe Plan B ought to be a required prescription for minors," and adding that he supports "Andy's [von Eschenbach's] decision."
- August 24, 2006: The FDA approves over-the-counter access to Plan B emergency contraception for women 18 years and older.
- March 23, 2009: The US District Court for the Eastern District of New York rules that the FDA politicized its decision in making emergency contraception available over-the-counter by acting "arbitrarily" and "capriciously" in restricting the drug to women 18 and over. The judge orders that the FDA not only reconsider and re-review its decision to impose age restrictions on access to EC, but immediately remove the existing age restriction for women 17 and over.
- April 22, 2009: The FDA complies with one part of the District Court's order by sending a letter to the Plan B manufacturer, Teva Pharmaceuticals, Inc., inviting them to submit an application to market Plan B to 17 year olds.
- June 24, 2009: The FDA approves the first generic version of Plan B called Next Choice™. This product is manufactured by Watson Pharmaceuticals, Inc and is available under the same conditions as Plan B – over-the-counter for consumers 18 and older and prescription-only for women 17 and younger.
- July 10, 2009: The FDA approves Plan B® One-Step, a single-pill emergency contraceptive, manufactured by Teva Pharmaceuticals, Inc. This product is marketed as over-the-counter for women 17 and older and prescription-only for women 16 and younger. At the same time, Plan B is made available over-the-counter to consumers 17 and older and prescription-only for women 16 and younger.
- August 24, 2009: Duramed's market exclusivity for over-the-counter Plan B expires, opening the market up for new over-the-counter emergency contraceptives.

- August 28, 2009: Next Choice is approved by the FDA as the first over-the-counter, Plan B generic. The product is available over-the-counter for women 17 years of age and older, and prescription-only for women 16 and younger.
- June 17, 2010: The FDA Reproductive Health Drugs Advisory Committee unanimously recommends the approval of ulipristal acetate 30mg (ella), a safe and effective emergency contraceptive product that delays ovulation and prevents pregnancy for five days after unprotected sex.
- August 13, 2010: The FDA approves ella, finding it safe and effective for women of all ages to use as a prescription-only product. This product is expected to be available for use in the fourth quarter of 2010.