



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

- *February 25, 1997:* The [Federal Register](#) announces that the FDA has concluded that certain combined oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as postcoital emergency contraception, and requests submission of new drug applications for this use.
- *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:* Food and Drug Administration (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 (CRR), on behalf of more than 70 medical and public health organizations, file a Citizen Petition with the U.S. Food and Drug Administration to make EC available over-the-counter (OTC).
- *April 21, 2003:* The manufacturer of Plan B files an application with the FDA to make it available OTC.
- *December 16, 2003:* An [FDA independent panel](#) of experts votes 23 to 4 to recommend Plan B be made available OTC, 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 OTC proposal to FDA, which would make it available OTC 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. [CRR files suit](#) against the Acting Commissioner of FDA.
- *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 OTC 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 OTC 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 OTC 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, Assistant Commissioner for Women's Health and Director of the FDA Office of Women's Health, resigns from the Agency on principle in response to the decision announced by FDA leadership to once again delay approval of Plan B, despite the recommendation of FDA scientific staff and advisory committees and the pledges received by Sens. Clinton and Murray.
- *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.
- *November 2005*: The Government Accountability Office (GAO) releases a [final report](#) documenting the FDA’s denial of Barr’s original application. The report deems the process leading up to the denial
- *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.
- *June 9, 2006*: FDA denies CRR's Citizen Petition on the grounds that it was not adequately supported by scientific evidence.
- *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 OTC 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 OTC 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 OTC.
- *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](#) OTC access to Plan B emergency contraception for women 18 years and older.
- *July 18, 2008*: Teva Pharmaceutical and Barr Pharmaceuticals [announce](#) they signed a definitive agreement under which Teva will acquire Barr.
- *March 23, 2009*: The US District Court for the Eastern District of New York [rules](#) that FDA acted "arbitrarily" and "capriciously" in restricting OTC access to women 18 and over. The judge orders FDA to re-review rationale for imposing any age restriction and simultaneously orders FDA to make Plan B available without a prescription to consumers 17 and older.

- *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 – OTC for consumers 18 and older and prescription-only for women 17 and younger.
- *July 10, 2009:* In compliance with the ruling, the FDA [approves](#) OTC availability of Plan B to consumers 17 and older. At the same time, the FDA approves a new drug, Plan B One-Step®, a single-pill emergency contraceptive, also to be available OTC for women 17 and older and prescription-only for women 16 and younger.
- *August 24, 2009:* Duramed’s market exclusivity for OTC Plan B expires, opening the market up for new OTC emergency contraceptives.
- *August 28, 2009:* Next Choice is approved by the FDA as the first OTC, Plan B generic. The product is available OTC 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 16, 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.
- *November 16, 2010:* CRR files a motion for contempt of court against the FDA for failing to follow District Court’s order that the FDA reconsider and re-review its decision to impose age restrictions on access to EC
- *December 1, 2010:* Watson Pharmaceuticals launches ella on the U.S. market where it is available by prescription-only to women of all ages.
- *December 30, 2010:* FDA approves second generic form of Plan B, [Levonorgestrel tablets](#), manufactured by Perrigo Pharmaceuticals, Inc.
- *February 7, 2011:* Teva Pharmaceuticals files an application with the FDA to re-label OTC Plan B One-Step without an age restriction with new data on actual use and [label comprehension](#) of adolescents.
- *December 7, 2011:* In an unprecedented move, HHS Secretary Kathleen Sebelius [overrules](#) FDA Commissioner Margaret Hamburg’s [recommendation to approve](#) Plan B One-Step for full OTC status saying there was not enough data on young adolescents. FDA issues a “complete response letter” to Teva.

- *December 12, 2011*: Secretary Sebelius [says](#) the door is open for Teva to come back to the FDA with more data and resubmit its application to make Plan B One-Step OTC for all ages, but does not provide a pathway for the company with in the complete response letter.
- *December 12, 2011*: FDA [denies](#) the Citizen Petition again.
- *December 13, 2011*: Federal District Judge Korman hears oral arguments on the CRR's motion for contempt against the FDA. He finds the contempt motion moot, but agrees to reopen the case and allows for the future addition of Secretary Sebelius as a defendant.

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