

## Important Milestones in the History of FDA-Approved Plan B®:

- *February 25, 1997:* U.S. Food and Drug Administration (FDA) [announces](#) oral contraceptives containing ethinyl estradiol and norgestrel or levonorgestrel are safe and effective for use as postcoital emergency contraception (EC), and requests submission of new drug applications for this use.
- *July 1999:* FDA [approves](#) Plan B®, a levonorgestrel emergency contraceptive pill, finding it safe and effective for women of all ages to use as a prescription product.
- *February 2001:* Reproductive Health Technologies Project (RHTP) and the Center for Reproductive Rights (CRR), on behalf of more than 70 medical and public health organizations, file a [citizen's petition](#) with FDA to make EC available over-the-counter (OTC).
- ***April 21, 2003:* The manufacturer of Plan B files an application with 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 6, 2004:* Dr. Steven Galson, Acting Director of the Center for Drug Evaluation and Research at FDA, overrides professional staff recommendations and issues a [“not approvable” letter](#) to Plan B’s manufacturer, citing concerns about young teens using the product and the need for more data.
- ***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 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.
- *July 15, 2005:* Sens. Clinton and Murray lift the “hold” on Crawford’s nomination to head the FDA after receiving assurances from US Department of Health and Human Services (HHS) Secretary Mike Leavitt that the FDA will act on the Plan B OTC application by September 1.
- *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.

- *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 "highly unusual."
- *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.
- *June 9, 2006:* FDA denies CRR's citizen's petition on the grounds that it was not adequately supported by scientific evidence.
- *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 a timetable.
- *August 24, 2006:* The FDA [approves](#) OTC access to Plan B emergency contraception for women 18 years and older.
- *July 18, 2008:* Teva Pharmaceutical [announces](#) they will acquire Barr Pharmaceuticals.
- *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, reopens the citizen's petition and simultaneously orders FDA to make Plan B available without a prescription to consumers 17 and older.
- *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 second generation product, Plan B<sup>®</sup> 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.
- *November 16, 2010:* CRR [files](#) a motion for contempt of court against the FDA for failure to revisit the age restriction.
- ***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 within the complete response letter.
- *December 12, 2011:* FDA [denies](#) the citizen's petition again.
  - *December 13, 2011:* Federal District Judge Korman will hear oral arguments on the CRR's motion for contempt against the FDA.

\*For more information please contact Lydia Stuckey at RHTP, [lstuckey@rhtp.org](mailto:lstuckey@rhtp.org).