



RHTP Closely Watching Plan B Resubmission
Possible Age Restriction Imposes Unnecessary Barriers for Young Women

For immediate release:
August 8, 2006

Contact: Chrissy Faessen
703-582-2777/ Chrissy.faessen@ddbissues.com

Washington D.C. – Today officials from Barr Pharmaceuticals, Inc. (Barr) and the Food and Drug Administration (FDA) met to discuss revisions to the pending application for over-the-counter (OTC) approval of Plan B, emergency contraception. Following the meeting, Barr announced they will submit an amended application within two weeks.

The issue of age has been a moving target in this application process. In December 2003 an FDA independent panel of experts recommended Plan B OTC access with no age restrictions. Between January and May 2004 three different layers of FDA staff concurred to recommend OTC access with no age restrictions. Then, in May 2004 Dr. Steven Galson, Acting Director of the Center for Drug Evaluation and Research (CDER) issued a “not-approvable” letter suggesting the company could reapply for OTC access with an age restriction of 16 and over. Following that letter, Barr submitted a revised proposal in July 2004 which would make Plan B available to women 16 years and older without a prescription. In August of 2005, then FDA Acting Commissioner, Lester Crawford confirmed that CDER had concluded that OTC access to Plan B was safe for women 17 and older. Finally, just last week the FDA announced they would work with Barr to approve Plan B OTC for women 18 and older.

“Clearly, the age restriction is nothing but a political fig leaf and, if imposed, will come at a real cost to young women who need it,” said Kirsten Moore, President and CEO of the Reproductive Health Technologies Project. “If restrictions on distribution are imposed, these are done in the name of political expedience – not because of any risks associated with this product. A clear path must be defined for lifting those restrictions in as short an amount of time as possible.”

Plan B is an FDA-approved, back-up birth control method that prevents pregnancy in the first few days after sex. Containing a concentrated dose of the progestin hormone found in daily birth control pills, Plan B reduces the risk of pregnancy by up to 89 percent when taken within 72 hours. (The sooner it is taken the more effective it is.) Emergency contraception could prevent up to half of the 3 million unintended pregnancies that occur each year in the U.S., but to make a real difference, women need to be able to get it quickly. Requiring a prescription is not only medically unjustified, it is also a known barrier to getting emergency contraception in time.

For more information including a complete timeline of the approval process for Plan B OTC please visit: <http://www.rhtp.org>

###