DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Christopher Shays
House of Representatives
Washington, D.C. 20515 0704

NOV 1 2005

Dear Mr. Shays:

Thank you for the letter of October 7, 2005, co-signed by 61 other members of the Pro-Choice Caucus in the House of Representatives concerning the Food and Drug Administration's (FDA or the Agency) review of the application by Barr Laboratories to market their product, Plan B, over-the-counter (OTC) instead of by prescription.

On September 1, 2005, FDA created a new public docket for the purpose of receiving comments regarding the advance notice of proposed rulemaking (ANPR) announced by FDA concerning the proposal to change Plan B to OTC status. This Docket No. 2005N-0345 will be open to receive comments until November 1, 2005. We have forwarded your letter to be included as a formal part of the docket record on this issue. Since over a thousand comments already have been received, the Center for Drug Evaluation and Research (CDER) soon will begin reviewing and compiling the suggestions and comments received on the several issues addressed in the rulemaking.

At the top of page two of your letter, however, you attribute to FDA a concern that the Agency has never expressed about the proposed Plan B switch to OTC status and we would like to correct the record on this matter at this time. Your letter says "The FDA cited the concern that easier access to EC might lead to promiscuity among women under the age of 16...." Although similar statements may have appeared in other writings outside of the Agency concerning this issue, FDA has never made such a statement. So there will be no confusion about the public statements FDA actually has made concerning the Plan B application, we are enclosing copies of the two press releases dated May 7, 2004, and August 26, 2005, that the Agency has issued concerning this application. In addition, we are enclosing a copy of the May 6, 2004, letter from Steve Galson, M.D., Director of CDER, to Barr Laboratories and the letter identified as NDA 21-045/S-011 from former Commissioner of Food and Drugs, Lester M. Crawford, D.V.M., Ph.D, to Duramed Research, Inc., concerning the ANPR.

Thank you again for your continued interest in this matter. An identical letter has been sent to your co-signers. If we can be of further assistance, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Associate Commissioner
for Legislation

4 Enclosures

cc: Docket Management Branch – HFA-305
(Docket No. 2005N-0345)