

July 30, 2010

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing to recognize and appreciate the progress that the Food and Drug Administration (FDA) has made to date in conducting an appropriate and impartial review of the clinical data on ulipristal acetate 30mg, also known as ella, for approval as an emergency contraceptive (EC) product. Both the FDA staff's review of this product and the unanimous recommendations made at the June 17, 2010 meeting of the agency's Advisory Committee for Reproductive Health Drugs affirm that ulipristal is effective in preventing pregnancy up to 120 hours after unprotected sex or contraceptive failure and has a safety profile compatible with new drug approval. With that strong scientific consensus, we look forward to the agency completing its review and hope to see it follow the approval recommendations of the Advisory Committee, giving women another safe and effective means to prevent unintended pregnancy.

We are pleased not only by the Advisory Committee's conclusions on safety and efficacy of ulipristal, but also by its unanimous conclusion that there is no evidence indicating a need for measures beyond the standard product labeling and health provider education to address possible off-label use of this product. Committee members noted that there were no safety signals in the data that such measures are necessary and warned against burdening ulipristal with unwarranted restrictions.

Additionally, we concur with the Advisory Committee that labeling the product to recommend pregnancy testing prior to dosing is an unnecessary Risk Management element for ulipristal. We also agree that such labeling would introduce an unnecessary medical intervention to the use of this product.

Finally, we believe this approval process is an opportunity to demonstrate that the agency's leadership is making good on its pledge to restore scientific integrity to FDA decision-making. We commend the agency for its work on this application to date and hope that the ulipristal review will proceed in a similarly transparent manner, consistent with FDA procedure and based on science, not politics.

Sincerely,

American Association of University Women  
American Congress of Obstetricians and Gynecologists  
American Medical Women's Association  
American Society for Reproductive Medicine  
American Society for Emergency Contraception  
Anne Burke, MD

Association of Women's Health, Obstetrics & Neonatal Nurses  
Black Women's Health Imperative  
Catholics for Choice  
Chelsea Polis, PhD  
Cynthia C. Harper, PhD; *Dept of Obstetrics, Gynecology & Reproductive Sciences, Bixby Center for Global Reproductive Health, University of California, San Francisco*  
EngenderHealth  
Gynuity Health Projects  
Heather Muno Prescott, PhD  
Ibis Reproductive Health  
Jewel C. Love, *SoulStirring, LLC*  
Jewish Women International  
Our Bodies Ourselves  
NARAL Pro-Choice America  
National Abortion Federation  
National Association of Nurse Practitioners in Women's Health  
National Council of Jewish Women  
National Family Planning and Reproductive Health Association  
National Institute for Reproductive Health  
National Latina Institute for Reproductive Health  
National Partnership for Women and Families  
National Research Center for Women and Families  
National Women's Health Network  
National Women's Law Center  
Physicians for Reproductive Choice and Health  
Planned Parenthood Federation of America  
Reproductive Health Technologies Project  
Rev. Dr. Carlton W. Veazey, President, CEO; *The Religious Coalition for Reproductive Choice*  
Sexuality Information and Education Council of the U.S.