DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 20 2006

1806 6 NOV 21 A9:51

Peggy A. Lautenschlager
Richard Briles Moriarty
Nelle Rohlich
Wisconsin Department of Justice
Post Office Box 7857
Madison, WI 53707-7857

Docket Number: 2006P-0223/CP1

Dear Ms. Lautenschlager, Mr. Moriarty, and Ms. Rohlich,

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved all of the issues raised in your citizen petition dated May 22, 2006, and supplement dated July 24, 2006. Your petition requests that FDA switch the emergency contraceptive drug Plan B (levonorgestrel, 0.75 mg) to over-the-counter status without age restrictions and that FDA exempt from prescription-dispensing requirements any new drug eligible for filing an abbreviated new drug application because of its equivalence to Plan B.

On August 24, 2006, FDA announced its approval of an amended supplemental new drug application (sNDA) sponsored by Duramed Research, Inc., a wholly owned subsidiary of Barr Pharmaceuticals, Inc., which permits Plan B to be marketed over-the-counter for women 18 years of age and older. As you know, on February 14, 2001, a group of citizen organizations submitted to FDA a citizen petition (Docket 2001P-0075) that is similar to yours requesting that FDA convert Plan B (and any generic version of the drug) from prescription-only to OTC status pursuant to 21 U.S.C. § 353(b)(3) and 21 C.F.R. § 310.200(b). On June 9, 2006, FDA denied that citizen petition on the ground that it was not adequately supported by scientific evidence.

The approval of OTC distribution to women 18 years of age and older has rendered moot some, but not all, of the issues that you raised in your petition. The other issues that you raise require additional review and consideration. FDA therefore has not reached a final decision on the portions of your petition that were not rendered moot by FDA's August 2006 sNDA approval decision. We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Nancy E. Boockes

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0223

LET 2