DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 2 6 2013

2013 SEP 27 P 2:07

Andrew M. Kaunitz MD, FACOG
Professor and Associate Chairman
Department of Obstetrics and Gynecology
University of Florida College of Medicine-Jacksonville
653-1 W. 8th Street
Jacksonville, FL 32209

David A. Grimes MD, FACOG, FACPM, FRCOG (Hon)
Clinical Professor, Department of Obstetrics and Gynecology
UNC School of Medicine
CB #7570
Chapel Hill, NC 27599-7570

Re: Docket No. FDA-2013-P-0380

Dear Dr. Kaunitz and Dr. Grimes:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 2, 2013. Your petition requests that the Agency amend the package labeling for the injectable contraceptive depot medroxyprogesterone acetate (DMPA) by removing the current black box warning regarding loss of bone mineral density and limiting use of the drug to two years.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett

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