



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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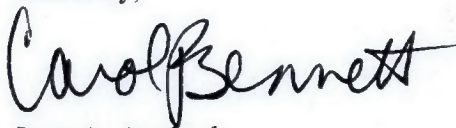
Re: Docket No. FDA-2013-P-0380

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,


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