FDA U.S. FOOD & DRUG ADMINISTRATION

William V. Williams
Contraceptive Study Group
620 South Eagle Road
Havertown, PA 19083

Re: Docket No. FDA-2019-P-2289

OCT 3 1 2019

Dear Mr. Williams:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on May 9, 2019. Your petition requests that the Agency remove the injectable contraceptive Depot medroxyprogesterone Acetate (DMPA; Depot Provera) from the market due to the risk of HIV transmission. Your petition also requests that all hormonal contraceptive products, regardless of route of administration, include additional warning language in the prescribing information due to a variety medical conditions which you identify as associated with use of hormonal contraceptive products.

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 J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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