DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

JAN 16 2014

Alan G. Minsk
Kelley C. Nduom
Arnall Golden Gregory LLP
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Re: Docket No. FDA-2013-P-0886

Dear Mr. Minsk and Ms. Nduom:

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 July 24, 2013. Your petition requests that the Agency determine that the drug, Jadelle (formerly referred to as Norplant II) (levonorgestrel) implant, 75 mg, new drug application (NDA) 020544, was voluntarily withdrawn from the market for reasons other than safety or effectiveness.

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,

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