DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 0 8 2013

J. Michael Nicholas, Ph.D.
Teva Women's Health, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355

Re: Docket No. FDA-2013-P-0163

Dear Dr. Nicholas:

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 February 11, 2013, submitted on behalf of Teva Pharmaceutical Industries, Ltd. Your petition requests that the Agency refrain from approving any Abbreviated New Drug Application referencing ParaGard T 380A (intrauterine copper contraceptive) until certain conditions are met.

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