DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUL 0 3 2013

James P. Reichmann

Re: Docket No. FDA-2013-P-0048

Dear Mr. Reichmann:

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 January 7, 2013. Your petition requests that the Agency:

(1) reclassify the drug ondansetron (Zofran) from pregnancy risk category B to risk category C, D, or X after the consideration of new safety information;
(2) notify OB/GYNs that: (a) no scientifically acceptable evidence has been published demonstrating efficacy, safety, or superiority of ondansetron over conventional treatments for nausea and vomiting during pregnancy, and (b) its use may lead to adverse maternal or fetal outcomes; and
(3) notify OB/GYNs that the continuous subcutaneous ondansetron pump may not be marketed or promoted in any way in the absence of FDA approval for the indication of treatment of nausea and vomiting in pregnancy.

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