



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 7, 2013

James P. Reichmann

Dear Mr. Reichmann:

Your petition to the Food and Drug Administration requesting the FDA to reclassify the drug Ondansetron(Zofran®) from pregnancy risk category B to C,D, or X after consideration of "new safety information", was received by this office on 1/7/2013. It was assigned docket number FDA-2013-P-0048/CP1, and it was filed on 1/7/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0048

ACK