



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

November 4, 2019

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Sent via email to: pia.p.krasnov@gsk.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to review four categories of information concerning the use of a prescription drug Zofran (ondansetron) in pregnancy was received by this office on 11/01/2019.

It was assigned docket number FDA-2019-P-5151. 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,

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)