



Sabine Luik, M.D.
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Research Triangle Park, NC 27709

RE: Docket No. FDA-2019-P-5151 4/27/2020

Dear Dr. Luik:

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 November 1, 2019. Your petition requests that the Agency review four categories of information concerning the use of Zofran (ondansetron) in pregnancy (Petition at 1).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -
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Digitally signed by Carol Bennett -S
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research