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Angie Dobbins
Grateful Doula Services
10554 14th Avenue S.
Seattle, WA 98168-1610

Re: Docket No. 2004P-0522/CP2

Dear Ms. Dobbins:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 29, 2004, pertaining to the off-label use of Cytotec (misoprostol) for cervical ripening and induction of labor. Your petition requests that the Agency require modifications to the drug's labeling and publicize certain adverse event reports related to this off-label use.

FDA has been unable to reach a decision on your petition because it raises significant/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.

Finally, I would like to call your attention to the fact that FDA recently issued a patient information sheet (PIS) to alert patients to certain risks associated with off-label, obstetric use of misoprostol. The PIS is available to the public on the FDA's Internet website at: <http://www.fda.gov/cder/drug/infopage/misoprostol/default.htm>.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0522

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