



MAY 23 2005

Food and Drug Administration  
Rockville MD 20857

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Maddy Oden  
The Tatia Oden French Memorial Foundation  
87 Hamilton Place  
Oakland, California 94612

Re: Docket No. 2004P-0522/CP1

Dear Ms. Oden:

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 23, 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.

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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