



Food and Drug Administration
Rockville, MD 20857

November 29, 2004

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

Dear Ms. Dobbins:

Your petition requesting the Food and Drug Administration to better regulate off-label use of Cytotec was received by this office on 11/29/2004. It was assigned docket number 2004P-0522/CP 2 and it was filed on 11/29/2004. 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,

/s/

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management