



Food and Drug Administration
Rockville, MD 20857

November 23, 2004

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

Dear Ms. Oden:

Your petition requesting the Food and Drug Administration to better regulate Off label drug use for CYTOTEC, was received by this office on 11/23/2004. It was assigned docket number 2004P-0522/CP1 and it was filed on 11/23/2004. 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/

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management