

Jaffe, Lyle D

From: angie@gratefuldoula.com
Sent: Monday, November 29, 2004 1:07 PM
To: Jaffe,Lyle D
Subject: RE: November 9, 2004 Petition

31 15 11 20 04

Dear Mr. Jaffe;

Per our conversation today; please be advised that to the best of my knowledge, the subject petition will have no impact to environment.

Thank you for your assistance with this.

Sincere regards,

Angie Dobbins

----- Original Message -----

Subject: November 9, 2004 Petition
From: "Jaffe, Lyle D" <LJAFJE@OC.FDA.GOV>
Date: Mon, November 15, 2004 8:31 am
To: "angie@gratefuldoula.com" <angie@gratefuldoula.com>
Cc: "Butler, Jennie C" <Jennie.Butler@fda.gov>, "Ortega, Gloria M" <GORTEGA@OC.FDA.GOV>

November 15,2004

Dear Ms. Dobbins:

I am responding to your November 9, 2004 petition requesting the FDA to establish a regulation for the drug Cytotec in its off-label use in obstetrics for cervical ripening and induction of labor. FDA has established procedural regulations that describe the appropriate format for petitions like yours, as well as certain matters on which information must be submitted. The regulations provide that if a petitioner fails to follow the appropriate format, or fails to submit information on a required subject, we cannot accept the petition for filing.

Your petition does not include an environmental impact statement as required by 21 CFR 10.30(b)C. For this reason, your petition is not acceptable for filing as a citizen petition. If you submit a claim for categorical exclusion under 21 CFR 25.30 or 21 CFR 25.31 by November 22, 2004, the Agency will accept the petition for filing. Please send the requested material to my attention by either conventional mail, e-mail or fax. I may

be reached by e-mail at ljaffe@oc.fda.gov or by fax at 301-827-6870. Attached are copies of the regulations that will enable you to provide the requested information. Please contact me by telephone at 301/827-6869 or by e-mail at ljaffe@oc.fda.gov if you need further assistance.

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management
301-827-6869
<<1030.htm>> <<2530.htm>> <<2531.htm>>