



APR 16 2003

Food and Drug Administration
Rockville MD 20857

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Donna Harrison, M.D.
American Association of Pro Life
Obstetricians and Gynecologists, et. al.
P.O. Box 414
Eau Claire, MI 49111

Re: Docket No. 02P-0337/CP1

Dear Dr. Harrison:

This letter informs you, pursuant to 21 CFR 10.30 (e)(2), that we are still actively considering the issues raised in your petition, dated August 20, 2002, requesting, among other things, that the Food and Drug Administration (FDA or agency) stay the approval of Mifeprex (mifepristone), thereby halting the distribution and marketing of the drug pending final action on the petition.

We apologize for the delay in responding to your petition. We can affirm that we are trying to complete our evaluation in as timely a manner as possible, given the complex science and policy issues raised. We will respond to your petition once that process has been concluded.

We also acknowledge receipt of Sandy Rios' March 4, 2003 letter to Dr. Mark McClellan and Daniel Troy, Esq., alerting the agency to an incident reported by the *Houston Chronicle*. We will consider that information as part of our evaluation of your petition and separately, if warranted.

Please feel free to send us any additional material, referencing the Docket number above, that you believe would be helpful in our evaluation of your petition. Finally, be assured that our evaluation of this petition is consistent with an evidence-based review and analysis applied to all petitions the agency receives.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

cc: Gene Rudd, M.D., Associate Executive Director, Christian Medical Association
Sandy Rios, President, Concerned Women for America
Jay Lefkowitz, Deputy Assistant to the President for Domestic Policy
Claude Allen, Deputy Secretary, Department of Health and Human Services

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