DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 26 2001

Ralph W. Hale, M.D., F.A.C.O.G.
Executive Vice President
American College of Obstetricians and Gynecologists
P.O. Box 96920
Washington, D.C. 20090

Re: Docket No. 00P-1603

Dear Dr. Hale:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on November 1, 2000, on behalf of the American College of Obstetricians and Gynecologists. Your petition requests that the Agency require the withdrawal of a letter issued by G. D. Searle & Co. on August 23, 2000, regarding misoprostol. You also request that the Agency review the misoprostol label and rescind any contraindications for use of misoprostol in pregnancy that are not warranted by scientific evidence.

FDA has not yet reached a decision on your petition because it raises 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.

Sincerely yours,

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

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