



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUN 13 2006

Roger C. Thies
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005

Re: Docket No. 2005P-0501/CP1

Dear Mr. Thies:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 20, 2005. Your petition requests that the Agency revise the FDA's guidance document entitled *Labeling for Combined Oral Contraceptives* so that the labeling of combined oral contraceptives have warnings relating to the risk of thromboembolic disease that are consistent with those required by the European Medicines Agency.

FDA has been unable to reach 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,

Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0501

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