



Food and Drug Administration
Rockville, MD 20857

December 20, 2005

Rogers C. Thies
Hyman, Phelps & McNamara, P.C
700 Thirteenth Street
Washington, DC 20005-5929

Dear Mr. Thies:

Your petition requesting the Food and Drug Administration to revise the FDA's guidance document entitled labeling for combined oral contraceptive so that the labels of combined oral contraceptive have warnings relating to the risk of thromboembolic disease that are consistent with those required by the European Medicines Agency, was received by this office on 12/20/2005. It was assigned docket number 2005P-0501/CP1 and it was filed on 12/20/2005. 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,

A handwritten signature in cursive script that reads "Jennie C. Butler".

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

2005P-0501

ACK 1