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NOV - 4 1998

Stuart J. Land
Arnold & Porter
555 Twelfth Street, N.W.
Washington, DC 20004-1202

Re: Docket No. 98P-0311/CP1

Dear Mr. Land:

Pursuant to 21 CFR 10.30(e)(2), this letter informs you that the Food and Drug Administration (FDA) is still considering the issues raised in your citizen petition submitted on May 13, 1998 on behalf of your client, Wyeth Ayerst Laboratories, Division of American Home Products Corporation, manufacturer of Premarin (conjugated estrogens) tablets. Your petition requests, among other things, that FDA deny approval of any new drug application for a mixture of five of the estrogens found in Premarin in the absence of safety testing of the type required for any new chemical entity.

FDA has been unable to respond to your request because it raises complex issues requiring extensive review and analysis by Agency officials. We will respond to your petition once we have reached a decision on your request.

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Woodcock", is written over a white background.

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