



OCT 15 2002

Michael Wess, M.D.  
Vice President, Scientific & Medical Affairs  
Amarin Pharmaceuticals, Inc.  
Two Belvedere Place, Suite 330  
Mill Valley, CA 94941

Re: Docket No. 02P-0170/CP1 & SUP1

Dear Dr. Wess:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated April 19, 2002, requesting that the Agency take certain action with respect to the abbreviated new drug applications (ANDAs) filed by Teva Pharmaceuticals and Ivax Pharmaceuticals for the generic formulation of Permax (pergolide mesylate).

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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,

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

02P-0170

LET 1