



117-305

Food and Drug Administration
Rockville MD 20857

JAN 11 2005

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David M. Fox
Hogan & Hartson
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: Docket No. 2004P-0320/CP1

Dear Mr. Fox:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated July 15, 2004. Your petition requests that FDA:

- (1) Refrain from granting final approval to Andrx's new drug application, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, that references Depakote (divalproex sodium delayed-release tablets) but that proposes a drug containing a different active ingredient than contained in Depakote, as well as any similarly situated applications; and
- (2) Initiate a public process to seek input from interested persons, including industry and consumer groups, on the use of section 505(b)(2) to obtain approval for drug products for which the only proposed difference from the reference drug is the active ingredient.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0320

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