



Food and Drug Administration
Rockville MD 20857

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MAR 24 2000

Robert A. Paarlberg
Senior Director, Global Regulatory Affairs
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001

Re: Docket No. 99P-0389/CP2

Dear Mr. Paarlberg:

I am writing to inform you that the Food and Drug Administration has not resolved the issues raised in your citizen petition received on September 28, 1999. Your petition requests that FDA not approve abbreviated new drug applications for topical dermatological drug products based on the principles outlined for establishing bioequivalence (specifically dermatopharmacokinetic studies) proposed in a draft guidance for industry on the products. You claim that the FDA should withdraw the draft guidance entitled "Topical Dermatological Drug Product NDA's and ANDA's -- In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies" and published in the June 18, 1999 Federal Register.

FDA has been unable to reach a decision on your petition because it raises issues requiring additional review and because of 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 we have reached a decision on your request.

Sincerely yours,

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

99P-0389

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