



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 21 2005

Charles J. Raubicheck
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Re: Docket No. 2004P-0339/CP1

Dear Mr. Raubicheck:

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 28, 2004. Your petition requests that FDA's Office of Generic Drugs refuse to accept for filing any abbreviated new drug application (ANDA) for the combination drug amlodipine besylate-benazepril hydrochloride unless the ANDA contains a study assessing bioequivalence to Lotrel (the reference listed drug) under both fed and fasting conditions.

FDA has yet 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 we have reached a decision on your request.

Sincerely,

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

2004P-0339

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