DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 14 2006

Peter O. Safir
Kelly A. Falconer
Covington & Burling
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington. D.C . 20044-7566
(202) 662-6000

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Re: Docket No. 2006P-0077/CP1

Dear Ms. Falconer and Mr. Safir:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on February 15, 2006, on behalf of Pfizer, Inc. Your petition requests that the Agency refrain from lifting the administrative stay currently in effect against the approval of the 505(b)(2) application from Dr. Reddy's Laboratories Ltd. for amlodipine maleate tablets (NDA 21-435) until 1) the expiration of Pfizer's pediatric exclusivity rights for Norvasc (amlodipine besylate) tablets on September 25, 2007, and 2) providing Pfizer advance notice of any decision to lift the stay.

FDA has been unable to reach a decision on your petition because the requested action involves complex issues requiring extensive review and analysis by Agency officials. 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,

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

2006P-0077

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