



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

February 16, 2006

**FILE COPY**

Peter O. Safir  
1201 Pennsylvania Avenue, N.W.  
P.O. Box 7566  
Washington, DC 20044-7566

Dear Mr. Safir:

Your petition requesting the Food and Drug Administration to refrain from lifting the administrative stay currently in effect against the approval of the Dr. Reddy's Laboratories Ltd. 505(b)(2) application for amlodipine maleate tablets (NDA 21-435) until after expiration of Pfizer's pediatric exclusivity rights for Norvasc (amlodipine besylate) on September 25, 2007, and after providing Pfizer advance notice, was received by this office on 02/15/2006. It was assigned docket number 2006P-0077/CP 1 and it was filed on 02/16/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0077

ACK 1