



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 11, 2000

Ms. Deborah Jaskot
Teva Pharmaceuticals USA
1510 Delp Drive
Kulpsville, PA 18960

Dear Ms. Jaskot:

Your petition requesting the Food and Drug Administration to determine that the approved application of Mylan for nifedipine extended-release tablets, was received by our office on 08/10/00. It was assigned docket number 00P-1446/CP 1 and it was filed on 08/11/00. Please refer to this docket number in the future correspondence 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
Dockets Management Branch

ACK 1