DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 6 2006

Peter R. Mathers, Esq.
Jennifer A. Davidson, Esq.
Kleinfeld, Kaplan and Becker, LLP
1140 19th Street, N.W.
Washington, D.C. 20036

Re: Docket No. 2006P-0444/PSA1

Dear Mr. Mathers and Ms. Davidson:

This letter responds to your petition for stay of action (petition) dated October 26, 2006, on behalf of Schwarz Pharma, Inc. (Schwarz). Your petition concerns the abbreviated new drug application (ANDA) of Paddock Laboratories, Inc. (Paddock) for moexipril hydrochloride tablets (ANDA 77-536). You request that the Food and Drug Administration stay any pending action to approve ANDA 77-536 unless and until the United States District Court for the District of Minnesota has ruled on Schwarz's motion to alter or amend judgment under Rule 59(e) of the Federal Rules of Civil Procedure. The judgment in question was the District Court's October 20, 2006, Memorandum Opinion and Order in Civil Action No. 05-832 ADM/JJG deciding, on Paddock's motion for summary judgment, that the product covered by ANDA 77-536 does not infringe U.S. Patent No. 4,743,450.

Your petition is moot because the District Court denied Schwarz's Rule 59(e) motion on November 20, 2006, and we did not approve ANDA 77-536 before that date. No further action on your petition is necessary, and we consider the petition closed.

Sincerely,

Randall W. Lutter, Ph.D.
Associate Commissioner
for Policy and Planning

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