## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES INC. and	)
MYLAN PHARMACEUTICALS INC.,	)
Plaintiffs,	) )
and	)
MUTUAL PHARMACEUTICAL CO., INC.,	)
Intervenor-Plaintiff,	)
v.	)
MICHAEL O. LEAVITT, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	) ) Civil Action No. 07-cv-579 (RMU) ) )
ANDREW C. VON ESCHENBACH, M.D., in his official capacity as COMMISSIONER OF FOOD AND DRUGS,	) ) )
UNITED STATES FOOD AND DRUG ADMINISTRATION, <i>et al.</i> ,	) ) )
Defendants,	)
and	)
TEVA PHARMACEUTICALS USA, INC.,	) )
and	) )
APOTEX INC.,	) )
Intervenor-Defendants.	)

## PLAINTIFFS' EMERGENCY APPLICATION TO TEMPORARILY RESTRAIN THE FDA FROM APPROVING ANY ADDITIONAL AMLODIPINE ANDAS IN DEROGATION OF MYLAN'S RIGHT TO 180-DAY MARKET EXCLUSIVITY

## Case 1:07-cv-00579-RMU Document 79 Filed 06/26/2007 Page 2 of 3

Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") respectfully submit this application for a preliminary injunction enjoining defendants, the U.S. Food and Drug Administration ("FDA"), Andrew C. von Eschenbach, M.D., in his official capacity as Commissioner of Food and Drugs, and Michael O. Leavitt, in his official capacity as Secretary of Health and Human Services, (collectively, "FDA") from taking any action to issue an approval of any Abbreviated New Drug Application for amlodipine besylate products in derogation of Mylan's right to 180-day exclusivity until the issue is finally decided on appeal.

The bases for the present application are fully set forth in the accompanying Memorandum in Support of Plaintiffs' Emergency Application to Temporarily Restrain the FDA from Approving any Additional Amlodipine ANDAs in Derogation of Mylan's Right to 180-Day Market Exclusivity and the Declaration of Shannon M. Bloodworth in Support thereof. Dated: June 26, 2007

Respectfully submitted,

/s/ David J. Harth

David J. Harth (#474632) HELLER EHRMAN LLP One East Main Street, Suite 201 Madison, Wisconsin 53703 (608) 663-7460

Shannon M. Bloodworth (#474925) Joseph P. Whitlock (#484247) HELLER EHRMAN LLP 1717 Rhode Island Avenue, NW Washington, D.C. 20036 (202) 912-2000

E. Anthony Figg (#345124) Steven Lieberman (#439783) Minaksi Bhatt (#434448) ROTHWELL, FIGG, ERNST & MANBECK PC 1425 K Street, NW Suite 800 Washington, DC 20005 (202) 783-6040

Stuart A. Williams Jill Ondos MYLAN LABORATORIES INC. 1500 Corporate Drive Suite 400 Canonsburg, Pennsylvania 15317 (724) 514-1840

Attorneys for Plaintiffs MYLAN LABORATORIES INC. and MYLAN PHARMACEUTICALS INC.