

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

MYLAN LABORATORIES, INC., *et al.*,)
)
 Plaintiffs,)
)
 v.)
)
 MICHAEL O. LEAVITT, Secretary,)
 Health and Human Services, *et al.*,)
)
 Defendants.)
)
 AND)
)
 TEVA PHARMACEUTICALS USA,)
 INC.,)
)
 APOTEX INC.,)
)
 MUTUAL PHARMACEUTICAL)
 CO., INC.,)
)
 Intervenor.)

Civil Action No. 07-0579 (RMU)

NOTICE OF FILING FDA DECISION

The government defendants, Michael O. Leavitt, Secretary of Health and Human Services, Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, and the Food and Drug Administration (FDA), hereby submit, pursuant to the Court’s Order of April 10, 2007, their decision regarding the approval of applications for generic versions of amlodipine besylate tablets. The Court’s April 10 Order further directed FDA to respond to Mylan’s TRO by 9:00 a.m. April 19 “[i]f the FDA decides to grant the ANDAs.” As reflected in the attached decision, FDA has decided not to approve ANDAs other than Mylan’s at this time. For this reason, the briefing contemplated in the Court’s April 10 Order is not appropriate. The government

defendants suggest that it may be appropriate to schedule a status conference regarding the next steps to be taken in this litigation.

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/s/

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