

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

MYLAN LABORATORIES, INC. <i>et al.</i> ,	:		
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Plaintiffs,	:	Civil Action No.:	07-579 (RMU)
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MICHAEL LEAVITT, <i>et al.</i> ,	:		
	:		
Defendants.	:		

ORDER

Pending before the court is the plaintiffs’ application for a temporary restraining order (“TRO”) to enjoin the defendant Food and Drug Administration (“FDA”) from issuing approvals for any abbreviated new drug applications (“ANDAs”) for amlodipine besylate. The plaintiffs seek this TRO claiming that they are entitled by statute to a 180-day period of exclusive marketing and sale of the drug’s generic version. They argue that their statutory right to exclusivity will be infringed if the FDA grants ANDAs to other generic drug manufacturers.

Government counsel has represented to the court that the FDA will now solicit the views of other interested parties on this matter by April 4, 2007 and will render an agency decision on April 11, 2007. Pursuant to this representation, the court need not enjoin agency action during the pendency of this matter at the agency. Government counsel has left open the possibility, however, that the FDA’s April 11, 2007 decision may simply constitute agency approval of the ANDAs. Such an eventuality would frustrate the process now in place for the court to evaluate the pending TRO application.

To ensure that all interested parties have the opportunity to advance their positions to the court on this matter prior to the FDA taking final action on the pending drug approvals, it is this 26th day of March, 2007 hereby

ORDERED that the FDA notify the court of its decision no later than April 11, 2007, and it is

FURTHER ORDERED that the FDA is enjoined from taking final agency action (i.e., granting any ANDAs at issue in this matter) from April 11, 2007 until April 13, 2007 at 5:00 pm to enable the court to rule formally on the plaintiffs' application for a TRO.

If the FDA decides to grant the ANDAs, the defendants' opposition to the plaintiffs' application for a TRO will be due by 9:00 am on April 12, 2007, and the plaintiffs' reply will be due by 9:00 am on April 13, 2007.

SO ORDERED.

RICARDO M. URBINA
United States District Judge