Mylan Announces Final FDA Approval for Topiramate Tablets

PITTSBURGH, Sept. 12 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that Mylan Pharmaceuticals Inc. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Topiramate Tablets, 25mg, 100mg and 200mg.

Topiramate Tablets are the generic version of Ortho-McNeil's Topamax® Tablets, which had U.S. sales of approximately $1.37 billion for the three strengths approved for the 12-month period ended June 30, 2006, according to IMS Health. Mylan also received tentative approval for the 50mg strength of Topiramate.

The FDA has confirmed that Mylan was the first generic company to file on the 25mg, 100mg and 200mg strengths of Topiramate and is therefore eligible for 180 days of market exclusivity. The FDA has indicated that the exclusivity will begin to run from the earlier of the commercial launch of the Mylan product or a court decision from which no appeal can be taken.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries: Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

For more information about Mylan, please visit www.mylan.com.

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CONTACT: Patrick Fitzgerald, Mylan Laboratories Inc., +1-724-514-1800
Web site: http://www.mylan.com