Mylan Sues FDA for Injunction Against Fentanyl Ruling

PITTSBURGH, June 23 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that it is filing suit against the Food and Drug Administration (FDA) in the U.S. District Court for the District of Columbia, seeking to restore final approval for its fentanyl transdermal system.

Robert J. Coury, Mylan's CEO and Vice Chairman of the Board stated: "Regardless of whether the FDA sided with Mylan or Janssen Pharmaceutica in its interpretation, we anticipated the courts would ultimately resolve this issue and believe the judicial process will result in confirmation of our position."

Mr. Coury went on to say: "In siding with Janssen and withdrawing Mylan's final approval, the FDA has acted contrary to multiple sections of the Federal Food, Drug, and Cosmetic Act and the Administrative Procedures Act, its published regulations and the legal precedent on point. We view this decision as yet another assault on the generic pharmaceutical industry. Among other problems created by the FDA's decision, this opinion encourages branded pharmaceutical companies to ignore the 45-day timeline to sue and effectively eliminates a generic company's ability to challenge patents that are nearing expiration."

Local procedural rules require a hearing in the suit to be held prior to July 23, 2004. As a result, Mylan has suspended annual earnings guidance.

A copy of the FDA's letter will be filed with the SEC with a Current Report on Form 8-K today.

Mylan Laboratories Inc. is a leading pharmaceutical company with four subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories, Inc. and Mylan Bertek Pharmaceuticals Inc., that develop, manufacture and market an extensive line of generic and proprietary products.

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

This press release includes statements that constitute "forward-looking statements", including with regard to the lawsuit to be filed against the FDA and the outcome of that suit. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: a ruling by the district court that is adverse to Mylan's position; other uncertainties and matters beyond management's control inherent in legal proceedings; and the other risks detailed in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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