Mylan Seeks Immediate Appeal on Fentanyl Ruling

PITTSBURGH, Aug. 18 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. District Court for the District of Columbia ruled against Mylan in its claim that the Food and Drug Administration (FDA) had improperly withdrawn final approval of Mylan's Abbreviated New Drug Application (ANDA) for its fentanyl transdermal patch. The district judge noted in his decision that both parties raised "compelling arguments," but that the relevant statutes "do not provide clear answers" and, therefore, the court would defer to FDA's interpretation. Mylan believes the relevant statutes are clear and intends to appeal the lower court's ruling immediately to the U.S. Court of Appeals for the D.C. Circuit.

Robert J. Coury, Mylan's Vice Chairman and CEO stated, "We are disappointed with the ruling because we continue to believe, as we said in June, that the FDA acted contrary to several sections of the Food, Drug and Cosmetic Act, the Administrative Procedures Act, FDA's regulations and legal precedent. The ruling also effectively eliminates generic companies' ability to challenge patents nearing expiration.

"In addition, the lower court ruling did not take into account the fact that Mylan has a separate appeal pending before the U.S. Court of Appeals for the Federal Circuit. In that appeal, Mylan seeks to overturn the March 2004 Vermont court ruling that Mylan's ANDA infringes Alza's patent. FDA's actions, and the D.C. district court's ruling, both depend on the Vermont court's order because that order was the sole basis for withdrawing Mylan's final approval. The Federal Circuit appeal, if successful, should provide another avenue to restore Mylan's final approval." Mylan anticipates a hearing on that appeal in October 2004.

A copy of the Court's ruling 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.

This press release includes statements that constitute "forward-looking statements", including with regard to the appeal of the lower court's ruling, the timing of the appellate hearing and the ultimate determination of these matters by the courts. 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 appellate courts that is adverse to the Company'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.

SOURCE Mylan Laboratories Inc.
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