



March 8, 2001

FDA Issues Warning Letter After Inspection

Lilly Working With FDA to Quickly Resolve Issues

Eli Lilly and Company (NYSE:LLY) announced today that it is working diligently to address issues raised as a result of a U.S. Food and Drug Administration inspection of its injectable product manufacturing facility in Indianapolis. The inspection cited Current Good Manufacturing Practice deficiencies in areas such as quality control, certain validation practices and other procedures.

"We are working in conjunction with the FDA - and with a keen sense of urgency - to resolve all issues raised as a result of the FDA inspection," said Scott Canute, vice president of manufacturing at Lilly. "We are confident we can correct all issues and believe that the timing of our new product launches will not be affected. Further, these corrections will not disrupt our ability to supply existing products. We remain confident of the safety and effectiveness of all products manufactured in this facility."

Lilly does not anticipate any material financial impact as a result of these manufacturing changes and therefore is not changing its previously announced earnings guidance.

On March 6, Lilly received a warning letter from the FDA following a routine inspection by the agency in February 2001 in connection with the company's application for approval of the rapid-acting intramuscular formulation of Zyprexa[®] (olanzapine). Lilly has action plans in place to address the FDA's observations. The company is working closely with the FDA and expects to be ready for reinspection within the next two months.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements based on management's current expectations concerning the company's efforts to resolve the Current Good Manufacturing Practice issues identified in the FDA warning letter and the potential impact of those issues on the company. Actual results may differ materially due to various factors. In particular, the timing and nature of the resolution of the CGMP issues will depend on the ability of the company to demonstrate to the satisfaction of the FDA the quality and reliability of its manufacturing controls and procedures. The failure to satisfy CGMP requirements established by the FDA could lead to delays in the release of products and in the approval of new drug applications, recalls or seizures, and other sanctions. For additional information about the factors that affect the company's business, please see Exhibit 99 to the company's latest Form 10-Q filed November 2000. The company undertakes no duty to update forward-looking statements.