



FOR IMMEDIATE RELEASE

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Luitpold Pharmaceuticals receives Warning Letter from FDA

(Shirley, NY) – September 2, 2011: Luitpold Pharmaceuticals, Inc., is notifying the public that it received a Warning Letter from the New York District Office of the Food and Drug Administration (“FDA”) yesterday. The Warning Letter results from an inspection of Luitpold’s facilities held by FDA from February 9, 2011, through March 15, 2011.

Luitpold responded to the Form 483 Notice of Inspectional Observations on April 5, 2011. The Warning Letter results from FDA’s review of Luitpold’s April 5, 2011 response to the 483 (and not updates to that response, described below, submitted since then.) In response to FDA’s concerns, Luitpold voluntarily suspended manufacturing operations from April 14, 2011 to May 16, 2011 during which time Luitpold focused its efforts on addressing the FDA observations, improving its processes and quality systems, and reviewing operations to ensure that it was capable of producing safe and effective drug products. Manufacturing resumed when an appropriate confidence level was attained following a full GMP audit.

Since Luitpold responded on April 5, 2011, Luitpold has made monthly updates to the Agency on its corrective actions to address the observations in the 483, and has met with the Agency to keep them up-to-date of our progress. In addition, the Company hired independent quality consultants to advise it and is manufacturing under third party oversight from those experts. The independent consultants have also conducted a Product Quality Assessment of each product prior to Luitpold resuming the manufacture of each product. Luitpold believes that it has already taken corrective actions to address most if not all of the observations in the Warning Letter, described in monthly updates submitted after April 5, 2011, and will submit a complete and detailed response to the Warning Letter to FDA by no later than September 22, 2011.

Luitpold is dedicated to only supplying safe, quality products, and has and will take all necessary action to resolve FDA’s concerns as expeditiously as possible.

Source: Luitpold Pharmaceuticals, Inc. (Shirley, NY)