



August 17, 2011

PMRS Certification of cGMP Compliance

Pharmaceutical Manufacturing Research Services Incorporated (PMRS) hereby certifies that, in our opinion, and to the best of our knowledge, all manufacturing, processing, packaging, labeling, control operations and holding of all drug product components, intermediates, bulk dosage forms, containers, closures, labeling, and finished drug products intended for human use are in compliance with the requirements set forth in the U.S. Code of Federal Regulations, Title 21, Parts 210 and 211.

Pursuant to Section 306(k) of the Federal (U.S.) Food, Drug, and Cosmetic Act, as amended by the Generic Drug Enforcement Act of 1992, PMRS hereby certifies that it has not and will not use, in any capacity, the services of any person debarred under subsections (a) and (b) of the Generic Drug Enforcement Act of 1992.

Pharmaceutical Manufacturing Research Services Incorporated (PMRS) has recently undergone successful regulatory inspections by both the United States FDA and the European MHRA. The most recent regulatory inspections and their status are listed below.

FDA Inspection: July 2011, No 483 observations were issued
November 2010, No 483 observations were issued
March 2009, No 483 observations were issued

MHRA Inspection: March 2009, UK MHRA, EU GMP certificate issued



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Charles J. Beaver
Director, Quality Management