FOR IMMEDIATE RELEASE

AMNEAL RECEIVES RARE FDA APPROVAL FOR EXTENDED PHENYTOIN SODIUM CAPSULES, USP

Hauppauge, NY (USA), May 4, 2009 – Amneal Pharmaceuticals is pleased to announce that it has received confirmation from the US FDA that its Extended Phenytoin Sodium Capsules, USP 100 mg are bioequivalent to Mylan's Extended Phenytoin Sodium Capsules. This marks an exceptional case where an Amneal generic stands as an AB-rated, therapeutically equivalent alternative to both the brand and the leading generic product.

Since extended phenytoin sodium has a Narrow Therapeutic Index (NTI), Amneal pursued a unique path for earning approval as a therapeutically equivalent alternative to both the brand and the leading generic. In addition to successfully completing and filing the required ANDA, which specified a bioequivalence study for comparison to the brand product, Dilantin® (Parke-Davis), Amneal also successfully completed a second bioequivalence study of comparison to the generic extended phenytoin sodium manufactured by Mylan.

On November 12, 2008, the FDA first granted approval to Amneal's Extended Phenytoin Sodium Capsules as being AB-rated to the brand, which is the normal procedure. Once that approval was granted, the FDA then reviewed the second bioequivalence study and Amneal's additional request, ultimately providing the second approval. This rare double approval by the FDA provides the critical evidence of therapeutic equivalence needed by the physician, pharmacist and patient to confidently switch to Amneal's phenytoin sodium product.

Extended phenytoin sodium is indicated for the control of generalized tonic-clonic (grand mal) and complex partial (psychomotor, temporal lobe) seizures and prevention and treatment of seizures occurring during or following neurosurgery. Amneal began shipping Extended Phenytoin Sodium Capsules, USP in the 100 mg strength on November 19, 2008. The product is available through wholesalers-distributors as well as directly to the trade.

Amneal Pharmaceuticals LLC, headquartered in Paterson, NJ, is a USA-based firm that develops, manufactures and distributes generic pharmaceutical products regulated and approved by the US FDA. Positioned as "Generic's New Generation," the company utilizes diverse R&D and manufacturing expertise to conceive breakthrough developments with lasting impact. Vigorous ANDA growth and broad product acquisitions are key features of Amneal's strategic growth plan, as is the company's commitment to building deep relationships with its customer base. Amneal delivers superior service levels, quality products, and dynamic value throughout the pharmaceutical industry.

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