

## **FOR IMMEDIATE RELEASE**

### **AMNEAL RECEIVES FDA APPROVAL FOR NIZATIDINE ORAL SOLUTION, THE FIRST GENERIC ORAL SOLUTION FOR AXID® IN THE MARKET**

Hauppauge, NY (USA), December 3, 2009 – Amneal Pharmaceuticals is pleased to announce that it has received U.S. FDA approval to manufacture Nizatidine Oral Solution in the 15 mg/mL strength effective November 18, 2009. It is an AA-rated, therapeutically equivalent alternative to Axid® Oral Solution (a licensed trademark of Braintree Labs). Nizatidine Oral Solution is the *first available generic in oral solution form* and marks Amneal's fourth liquid approval. It represents the company's first exclusive generic – Amneal has 180-day exclusivity to market the product beginning from the date of first shipment.

Amneal will sell Nizatidine Oral Solution, a clear yellow, peppermint-flavored syrup, in a 16 fl oz/473 mL lightweight, UV-protected plastic bottle. Amneal's generic product does not require refrigeration.

Nizatidine Oral Solution is an anti-acid indicated in the treatment and prevention of ulcers, the treatment of heartburn and the stomach disorder GERD (gastroesophageal reflux disease) as well as conditions associated with excess acid secretion. Nizatidine belongs to a class of medications known as H2-blockers that inhibit the action of histamine on stomach cells, thus reducing stomach acid production.

Amneal will begin shipping Nizatidine Oral Solution in the 15 mg/mL strength as of January 4, 2010 and will have the product available through wholesalers-distributors as well as directly to the trade. The liquid solution is manufactured in Amneal's cGMP-compliant Branchburg, NJ facility.

“The approval of Nizatidine is a significant milestone in the continued growth of Amneal, since it is our first ANDA approval as a ‘First-to-File’ application,” said Chirag Patel, President of Amneal. He added, “Our total commitment to obtaining rapid ANDA approvals, manufacturing the highest quality products and delivering outstanding customer service has fueled Amneal's year-over-year prescription growth of 114%, the highest in the generics industry according to IMS Health.”

Nizatidine Oral Solution joins Amneal's diversified portfolio of 250 products in the company's on-line product catalog at [www.amneal.com](http://www.amneal.com). Launched in September, the comprehensive web catalog is designed for easy customer and patient access to essential information, images and literature such as product outserts, labels, patient medication guides, MSDS (material safety data sheets) and high-resolution product photos.

Amneal Pharmaceuticals LLC, headquartered in Hauppauge, NY is a U.S.-based firm that develops, manufactures and distributes generic pharmaceuticals regulated and approved by the U.S. FDA. Known as “Generic's New Generation”, the company utilizes its newly

expanded R&D and manufacturing capabilities to conceive breakthrough developments with lasting impact for a robust product pipeline. Rapid ANDA approvals and diverse product acquisitions are key to Amneal's aggressive growth strategy, as is the company's strong commitment to deep customer relationships and maximum value creation. Amneal delivers high quality products, superior service levels and dynamic value throughout the pharmaceutical industry. For more information, visit [www.amneal.com](http://www.amneal.com).

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