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U.S. Food and Drug Administration and Xanodyne Agree on a Plan to Keep Propoxyphene Products available as Treatment Options for the Management of Mild to Moderate Pain

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FOR IMMEDIATE RELEASE

Newport, KY --- July 07, 2009 --- Xanodyne Pharmaceuticals, Inc. has reached an agreement with the U.S. Food and Drug Administration (FDA) to keep propoxyphene-containing products Darvon® (propoxyphene hydrochloride), Darvon-ES® (propoxyphene napsylate), Darvocet-N® 50 & Darvocet-N® 100 (propoxyphene napsylate/acetaminophen) available as treatment options for the management of mild to moderate pain. The action follows a joint committee meeting with the U.S. Food and Drug Administration (FDA) and Life Support Drugs Advisory Committee (ALSDAC) and Drug Safety and Risk Management Committee (DSRMAC) that was held on January 30, 2009.

The action by the FDA requires the manufacturers of propoxyphene-containing products to: change the product label to strengthen important safety information about certain drug-drug interactions, develop and distribute a patient medication guide and provide clinical data to further evaluate cardiac safety.

"This is an important decision by the agency which demonstrates the value of these products for patients who suffer from pain. We will work diligently with the agency in the coming months to ensure compliance with the items referenced in the ruling," said Michael Valentino, President and Executive Officer.

Xanodyne is committed to supporting the appropriate use of its medications according to product labeling. The diverse nature of pain and the difficulty in appropriately treating pain underlies that physicians and patients must have available numerous therapeutic options, including propoxyphene, for effective management of mild to moderate pain.

The most frequently reported side effects of propoxyphene-containing products include constipation, sedation, nausea, and vomiting. Constipation, abdominal pain, skin rashes, lightheadedness, weakness, euphoria, dysphoria, hallucinations, and minor visual disturbances have also been reported. For additional important safety and dosing information, please see the full prescribing information at www.xanodyne.com.