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## US WorldMeds Receives \$3 Million from NIDA to Develop Drug That Relieves Withdrawal Symptoms in Opiate Dependent Patients

*Louisville, Kentucky – February 24, 2011* - US WorldMeds LLC, a specialty pharmaceutical company, today announced that it has been awarded a nearly \$3 million grant from the National Institute on Drug Abuse (NIDA), an institute within the U.S. National Institutes of Health (NIH). The grant will advance the company's pursuit of Food and Drug Administration (FDA) approval for Lofexidine, the first non-narcotic and non-addictive medication for the treatment of acute withdrawal from short-acting opioids, such as heroin and commonly used prescription pain medications like Vicodin®, Lortab®, and Oxycontin®.

The award is one of a select number of grants given nationwide by NIDA with the intention of accelerating the development of safe and effective medications for the treatment of substance-related disorders, with the ultimate goal of moving closer to or gaining FDA approval of medications for the treatment of these disorders.

Opioid abuse and dependence is a serious and growing problem in the US, with an estimated 5.2 million nonmedical users of prescription opiate pain killers, 1 million heroin addicts in the US, and recent articles suggesting that abuse is spreading into rural and suburban areas. There is an unmet medical need in the opioid-dependent population, with only two FDA-approved drugs, methadone and buprenorphine, currently available to treat opioid withdrawal. Both are opiate products that effectively operate as replacement or substitution therapies, have abuse potential and are themselves controlled substances. FDA approval of lofexidine hydrochloride will enable the entrance of the first non-narcotic, non-addictive product to the market for the treatment of opioid withdrawal, the first hurdle in recovery from opioid dependence. The research funded by NIDA is required by the FDA to understand how lofexidine works in the body so that appropriate dosing, meal requirements, the safety of combination with other treatment drugs, and safety considerations for patients with poor liver and kidney functions can be evaluated. US WorldMeds will utilize the grant funds to conduct the research over the next three years.

NIDA reviewers gave an outstanding rating to US WorldMeds' application for Lofexidine and noted that FDA approval of the drug would represent a significant advancement in the treatment of opiate withdrawal and, possibly, other addictive disorders.

"Lofexidine will be an excellent addition to our line of products," said P. Breckinridge Jones, CEO of US WorldMeds. "Once commercially available, it will expand the treatment options available to physicians and patients battling opiate addiction-- an emotionally, physically, and socioeconomically devastating disease. We are excited to

be able to continue our development efforts of this important product with NIDA's support."

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