



FDA News

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Media Inquiries:
Rita Chappelle, 301-796-
4672

Consumer Inquiries:
888-INFO-FDA

FDA Takes Action Against KV Pharmaceutical Company *Company Making, Marketing and Distributing Adulterated and Unapproved Drugs*

The FDA announced a Consent Decree of permanent injunction filed March 2, 2009, enjoining KV Pharmaceutical Company, its subsidiaries ETHEX Corporation and Ther-Rx Corporation, and its principal officers from making and distributing adulterated and unapproved drugs. The injunction against KV and the other defendants, once entered by the court, will prevent them from manufacturing and shipping drugs until the firm obtains FDA approval. It will remain in place until the defendants sustain continuous compliance with FDA's current Good Manufacturing Practice (cGMP) and new drug approval requirements for six years.

The Consent Decree also enjoins KV's officers David A. Van Vliet, president and chief executive officer; Rita E. Bleser, president of the pharmaceutical division; Jay S. Sawardeker, vice president of corporate quality, and Marc S. Hermelin, former chief executive officer and a member of KV's Board of Directors, from manufacturing and distributing any drug at or from KV's facilities until the company's procedures and products are brought into compliance with the law.

KV Pharmaceutical manufactures, processes, packages, labels, holds, and distributes drugs from various locations in St. Louis, Mo., and the surrounding area. FDA inspected KV between December 2008 and February 2009, and found that the company had significant cGMP violations and continued to manufacture unapproved drugs. As a result of those inspections, which led to this action, KV recalled all products manufactured and distributed from its facilities.

“The FDA requires companies to manufacture drugs in accordance with the current good manufacturing practice standards and to comply with FDA approval requirements,” said

Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research (CDER). "Consumers need to be confident that drugs meet our manufacturing requirements for identity, strength, purity, and quality, and have been evaluated by the FDA for safety and efficacy."

Under the terms of the Consent Decree, the defendants cannot resume manufacturing and distributing drugs until both an independent expert and FDA officials conduct inspections of their facilities and certify that they are in compliance with the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations, and the decree. The Consent Decree also requires the defendants to destroy all drugs they recalled between May 2008 and Feb. 3, 2009. Those drugs are currently in their possession.

If the defendants fail to comply with any provision of the Consent Decree, the Act, or FDA regulations, FDA may order the firm to again stop manufacturing and distributing drugs, recall the products, or take other corrective actions.

"The FDA will carefully monitor the provisions of this injunction against the KV Pharmaceutical Company to ensure compliance," said Michael Chappell, the acting associate commissioner of FDA's Office of Regulatory Affairs. "Companies should know that FDA will investigate and take action against other marketers of unapproved drugs."

The Consent Decree subjects the defendants to liquidated damages of \$15,000 per day if they fail to comply with any of the provisions of the decree, and the payment of an additional \$15,000 for each violation, up to \$5 million per year.