

KV Pharmaceutical Subsidiary Pleads Guilty To Two Felonies Regarding Oversized Drugs

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Judge Sentences St. Louis-Based Company to Pay \$27.6 Million in Fines, Restitution and Forfeitures

Washington /PRNewswire-USNewswire/ -- Ethex Corporation, a wholly owned subsidiary of St. Louis-based drug manufacturer, KV Pharmaceutical Company, pleaded guilty to two felonies and was sentenced today in connection with the manufacturing of oversized prescription drug tablets, the Justice Department announced today. The government had charged that, despite having knowledge that the two drugs did not meet required specifications, Ethex violated the law by intentionally withholding this information from the Food and Drug Administration (FDA). Given the seriousness of Ethex's conduct and the risk it posed to consumers of its drugs, the Justice Department pursued felony charges.

According to charges presented in U.S. District Court in St. Louis today, Ethex failed to submit required "field alert reports" to the FDA in 2008 concerning two drugs, propafenone and dextroamphetamine sulfate. Following the recommendations of a plea agreement that was filed today, Judge E. Richard Webber sentenced Ethex to pay a fine of more than \$23.4 million, pay approximately \$2.3 million in restitution to Medicare and Medicaid for their approximate losses, and forfeit nearly \$1.8 million to the United States.

Under the Food, Drug and Cosmetic Act, a drug manufacturer must thoroughly investigate why a drug fails to meet specifications, whether or not the drug has been distributed into interstate commerce. Moreover, when a manufacturer receives information concerning a significant chemical change in a distributed drug or a failure of a distributed drug batch to meet specifications, it is required to promptly file a field alert report with the FDA. A manufacturer's failure to file such a report, if done with the intent to defraud or mislead, is punishable by a term of up to five years' probation and a fine of \$500,000 or twice the gross amount gained from the offense.

The government had alleged that in May 2008, KV and Ethex received complaints from a pharmacy in California and a distributor in Canada of oversized morphine sulfate pills, a pain-relief medication which had been manufactured by KV and distributed by Ethex. In response to the complaints, KV recalled specific lots of morphine sulfate in June 2008 and filed a field alert report regarding the oversized tablets with the FDA.

According to the charges, a KV internal investigation that began in May 2008 discovered sporadic instances of various oversized KV-manufactured drugs, including morphine sulfate, propafenone and dextroamphetamine sulfate. Propafenone is an anti-arrhythmia drug that is used to treat some kinds of heart disease. Dextroamphetamine sulfate is used

to treat attention deficit disorder in children. The charges alleged that despite the fact that KV's internal investigation uncovered evidence of various oversized propafenone and dextroamphetamine sulfate tablets, Ethex did not file the required field alert reports with the FDA.

"Even though they were aware of serious manufacturing problems concerning their oversized drugs, Ethex failed to notify the FDA as required by law," said Assistant Attorney General Tony West, who heads the Justice Department's Civil Division. "The Justice Department will vigorously prosecute those who pursue profits at the expense of consumer safety."

The case was investigated by the FDA's Office of Criminal Investigations and is being prosecuted by the U.S. Attorney's Office for the Eastern District of Missouri and the Civil Division's Office of Consumer Litigation at the Justice Department. Additional assistance is being provided by the FDA's Office of Chief Counsel.

SOURCE U.S. Department of Justice

KV to close Ethex unit and plead guilty to charges

By MARLEY SEAMAN
The Associated Press
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NEW YORK -- KV Pharmaceutical Co. said Thursday it will shut down its Ethex generic drug unit and plead guilty to criminal charges alleging Ethex failed to promptly inform regulators about dangerous manufacturing problems.

KV said it will shut down Ethex Corp. because after the plea, it would probably be excluded from government programs. The company will also pay a total of \$27.6 million to resolve a government investigation into its business, which has had to recall dozens of drugs because its manufacturing practices did not meet federal standards.

The charges concern Ethex's failure to file field alerts, or urgent notices about potential safety threats, with the Food and Drug Administration. The alerts concern two drugs: dextroamphetamine, an ingredient in the attention deficit hyperactivity disorder drug Adderall, and propafenone, which is used to treat cardiac arrhythmia, or irregular heartbeats.

The FDA told KV to stop making some time-release cough, cold, and gastrointestinal drugs in 2008. It said KV continued to make the drugs, and in July of that year, the agency seized more than \$24 million in unapproved products.

KV had to issue repeated recalls in late 2008 and early 2009 because some batches of its drugs contained pills that were oversized, which could have led patients to overdose

accidentally. Most of the recalled products were made by Ethex, but some were made by the Ther-Rx specialty drug division.

Late that year, CEO Marc Hermelin left his post after more than 30 years on the job. He was replaced by David Van Vliet, who had been in charge of Ethex.

The payments include \$25.8 million in fines and restitution, \$2.3 million of which will be paid to the federal government. Ethex also will not contest a \$1.8 million administrative forfeiture, KV said.

KV is still not able to resume sales of generic drugs affected by the recalls. But Wall Street responded positively to news that the investigations are being resolved.