



FDA NEWS RELEASE

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Federal Government obtains permanent injunction against Deltex Pharmaceuticals Inc.

Company charged with manufacturing and distributing drugs in violation of federal law

The U.S. Food and Drug Administration today announced that the U.S. District Court for the Southern District of Texas entered a consent decree of permanent injunction against Deltex Pharmaceuticals Inc., of Rosenberg, Texas, its president, Kabir Ahmed, and vice president, Mohidur R. Khan.

The consent decree permanently prohibits/stops the company, Ahmed, and Khan from manufacturing and distributing drug products until Deltex's manufacturing operations and products are in compliance with federal law and the terms of the consent decree.

Deltex is a contract manufacturer and distributor of prescription and over-the-counter (OTC) drug products. The government's complaint, filed by the U.S. Department of Justice, detailed violations of the Federal Food, Drug, and Cosmetic Act involving manufacturing and distributing unapproved, adulterated, and misbranded drugs. Specifically, Deltex failed to obtain required FDA approval for its prescription drug products, failed to comply with FDA regulations governing OTC drug products, and failed to comply with current good manufacturing practice (cGMP) requirements.

"This injunction shows that FDA will seek enforcement action against companies that are identified as being in violation of our manufacturing and drug approval requirements," said Dara A Corrigan, FDA's associate commissioner for regulatory affairs.

The FDA provided ample prior notice to Deltex, a company with a history of significant violations of cGMP requirements, to cease marketing unapproved, adulterated, and misbranded drugs. FDA inspections of Deltex repeatedly found evidence that the defendants manufacture and distribute unapproved, adulterated, and misbranded drugs.

The FDA issued a Warning Letter to Deltex for manufacturing unapproved drugs and for deviations from cGMP requirements. Since the issuance of the Warning Letter, the company continued to manufacture and distribute unapproved new drugs and continued

to fail to comply with cGMP regulations.

Under the terms of the consent decree, the defendants cannot resume manufacturing and distributing any drug until Deltex complies with cGMP requirements. Additionally, the defendants cannot resume distributing any drug until such drug is approved by FDA or it complies with OTC drug monographs, the regulatory mechanism for legally marketing many non-prescription or OTC drugs.

Further, the defendants must recall drugs that were manufactured and distributed since Oct. 31, 2008 from their customers and destroy the recalled drugs, and additionally advise their customers to recall products at the retail level. The consent decree also subjects the defendants to penalties of \$2,500 per day if they fail to comply with any of the provisions of the consent decree, and an additional \$500 for each violation.