Major Manufacturer of Unapproved and Adulterated Drugs

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April 25, 2007，The U.S. Food and Drug Administration (FDA) announced the entry of a Consent Decree of Permanent Injunction against PharmaFab Inc., its subsidiary, PFab LP, and two company officials, Mark Tengler, PharmaFab's president, and Russ McMahen, PFab's vice president of scientific affairs, to stop the illegal manufacture and distribution of prescription and over-the-counter drug products. The products are illegal because they are not produced according to the required current good manufacturing practice (CGMP) and many also lack required FDA approval. The case was filed in the United States District Court for the Northern District of Texas.

"Drug approval and CGMP compliance are part of the foundation of drug safety," said Steven K. Galson, M.D., M.P.H, director of FDA's Center for Drug Evaluation and Research (CDER). "When companies and individuals choose not to comply with the law, FDA must deal with these problems decisively."

PharmaFab is a major contract manufacturer and distributor of more than 100 different prescription and over-the-counter drug products, including cough and cold products, ulcer treatments, and postpartum hemorrhage products. Consumers who have products manufactured by PharmaFab should consult with their physician.

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