



FDA News

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FDA Obtains Permanent Injunction Against Scientific Laboratories, Inc.
Company manufactures and distributes unapproved and adulterated drugs

The U.S. Food and Drug Administration (FDA) today announced that Scientific Laboratories Inc., and its president, Rajeshwari Patel, and chief executive officer, Amit Roy, have signed a Consent Decree of Permanent Injunction and are barred from manufacturing and distributing drug products until they bring their manufacturing operations into compliance with law and obtain approval for their products.

Scientific Laboratories is a contract manufacturer and distributor of various prescription cough and cold products. The government's complaint, filed by the U.S. Department of Justice, alleged violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The company failed to seek required FDA approval for some of its products and failed to comply with current good manufacturing practice requirements (CGMP).

"The FDA will not allow a company to put the public's health at risk," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "These unapproved new drugs have not undergone FDA review for safety and efficacy and may pose potential health risks."

The unapproved new drugs manufactured and marketed by Scientific Laboratories as prescription cough and cold products include: B-Vex Suspension, Ben-Tann Suspension, D-Tann Suspension, D-Tann AT Suspension, D-Tann CT Suspension, D-Tann DM Suspension, D-Tann HC Suspension, Dur-Tann DM Suspension, Duratan DM Suspension, L-All 12 Suspension, Nazarin Liquid, and Nazarin HC Liquid. Because these drugs have not undergone FDA review nor received approval, their safety and effectiveness have not been established. Additionally, the FDA has not reviewed the adequacy and accuracy of the directions and warnings in their labeling.

The FDA had warned Scientific Laboratories against violating the FD&C Act and about the risk of enforcement action if it failed to take corrective measures.

"The FDA will take action against companies and their executives who violate the law and endanger public health," said Margaret O'K. Glavin, associate commissioner for Regulatory Affairs. "The FDA will carefully monitor the provisions of this injunction as well as investigate and take action against other marketers of unapproved drugs."

The consent decree bars the defendants from manufacturing and distributing any drug until they obtain required FDA approval and fully comply with CGMP requirements. The defendants must destroy their illegal drugs. The consent decree also allows the FDA to order the defendants to shut down in the event of future violations. It also subjects the defendants to liquidated damages in the amount of \$5,000 per day if they fail to comply with any of the provisions of the decree, and an additional sum of \$5,000 for each violation, up to \$1 million per year.

If patients have these products in their homes, they should discuss with their health care provider whether to discontinue use of the products and to find alternative therapy. Pharmacies should discontinue dispensing these products.

In June 2006, the FDA issued a guidance document titled, "Marketed Unapproved Drugs—Compliance Policy Guide" (CPG). This CPG makes clear that companies may not market drugs that require approval without first establishing, through applications for approval, that the products are safe and effective. The CPG also explains that FDA may take action against manufacturers and marketers of unapproved drugs that violate other provisions of the FD&C Act, including CGMP requirements.

The decree was signed Thurs., May 8, 2008 by Judge William D. Quarles, Jr., in the U.S. District Court for the District of Maryland.