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FDA Blocks Sale of Illegal Drugs U.S. District Judge Issues Injunction Against Florida Company

The U.S. Food and Drug Administration (FDA) today announced a permanent injunction shutting down operations at Pharmakon Labs of Florida. The company manufactured and distributed cough and cold liquids, tablets and caplets.

Following inspections by FDA and a trial in U.S. District Court, Judge Richard A. Lazzara found that drug products sold by Pharmakon Labs, Inc., its president Abelardo L. Acebo, and its secretary/treasurer Edward R. Jackson (the defendants) did not meet current good manufacturing practice (cGMP) standards and other legal requirements.

Judge Lazzara stated that he was "simply unwilling as a court of equity to place the health, safety, and welfare of the general public at risk in order to accommodate the economic well-being of Defendants." Thus, the defendants were ordered to stop manufacturing and distributing drugs until they become compliant with CGMP standards to the satisfaction of FDA and obtain marketing approvals.

"This action by Judge Lazzara sends a strong signal that FDA will take action against drugs that fail to meet quality standards," said FDA Commissioner Dr. Lester M. Crawford. "As the nation's top enforcer of manufacturing standards, the FDA will continue to ensure that drugs being sold in this country meet those crucial requirements."

The defendants have a long history of continued violations of the Federal Food, Drug, and Cosmetic Act. The government's initial complaint alleged numerous manufacturing violations documented in four inspections dating back to 2001.

In September 2001, the company received a warning letter citing failure to label proper dosage; failure to establish qualification for manufacturing equipment ancillary systems; failure to validate or establish written procedures for the validation of equipment operations, water quality, or computer software used to calculate batch formulations, and failure to periodically monitor the quality of water used for manufacturing and cleaning.

FDA later added charges related to Pharmakon's manufacture and distribution of unapproved new drugs, as part of the agency's longstanding policy to seek relief for all legal violations by a firm at the same time.

The government's request for a permanent injunction was based on the defendants' demonstrated unwillingness to comply with the law.

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