



# Department of Justice

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## **FEDS SEIZE DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS FROM HI-TECH PHARMACEUTICALS**

Atlanta, GA—At the request of the U.S. Food and Drug Administration (FDA), the U.S. Attorney's Office for the Northern District of Georgia filed a Complaint for Forfeiture against “Lipodrene,” “Stimerex-ES,” and “Betadrene” – dietary supplements manufactured, marketed, and distributed by Hi-Tech Pharmaceuticals, Inc. (“Hi-Tech”), that are labeled as containing 25 mg of ephedrine alkaloids per tablet. The Complaint for Forfeiture also included the ephedrine alkaloid raw materials used to manufacture these dietary supplements. The U.S. Marshals Service yesterday began seizing these dietary supplements and ingredients located at Hi-Tech facilities in Norcross, Georgia. Through this action, FDA, in conjunction with the Department of Justice, prevented approximately \$3,000,000 worth of products from reaching consumers and endangering their health.

“FDA continues to warn consumers to avoid consumption of dietary supplements containing ephedrine alkaloids,” said Andrew von Eschenbach, MD, Acting FDA Commissioner. “We will continue to do all we can to protect the public health against these dietary supplements that have been found to cause serious illness and injury.”

United States Attorney David E. Nahmias said of today’s enforcement action, “The FDA has advised that these dietary supplements can be dangerous to the health of the citizens in our communities. This office and the FDA are taking the legal steps to safeguard the health and safety of people who may not know or understand the dangers that they face using ephedrine alkaloid products.”

U.S. Marshals seized more than 200 cases of finished product, more than 200 boxes of bulk tablets, nine 25 kilo drums of ephedrine alkaloid raw material. The product labels state that the maximum recommended dosage of ephedrine for a healthy adult is 100 mg in a 24 hour period. The seized products and raw material are valued at approximately \$3,000,000.

Ephedrine alkaloids are adrenaline-like stimulants that can have potentially dangerous effects on the heart. Recent studies have confirmed that ephedrine alkaloids raise blood pressure and otherwise stress the circulatory system, effects that are linked to

adverse health effects like heart attacks and strokes. Based on this and other evidence in the scientific literature, FDA issued a rule in February 2004 declaring that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury. Since this rule became effective in April 2004, the government has executed six seizures against numerous products.

Hi-Tech has previously filed a lawsuit against FDA seeking to prevent the agency from enforcing the 2004 rule declaring dietary supplements containing ephedrine alkaloids to be adulterated. The United States recently moved to dismiss that lawsuit, which is currently pending in the United States District Court for the Northern District of Georgia.

Assistant United States Attorneys Dahil D. Goss and Stephen H. McClain are representing the United States in the cases in Atlanta.

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