



# Department of Justice

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## SENTENCINGS IN HUMAN GROWTH HORMONE DISTRIBUTION CASE

### **Medisca and its President Sentenced in Connection with their Previous Pleas to Distributing Somatropin Using Misleading Claims**

ALBANY, NY - Richard S. Hartunian, United States Attorney for the Northern District of New York, and Mark Dragonetti, Special Agent-In-Charge of the New York Field Office of the United States Food and Drug Administration Office of Criminal Investigations announced that MEDISCA, INC., a New York corporation located in Plattsburgh, New York, and its President, ANTONIO DOS SANTOS, age 63, of Montreal, Canada, were sentenced today in federal court in Albany. United States Magistrate Judge David R. Homer sentenced MEDISCA to pay a \$10,000 fine, and DOS SANTOS to pay a \$5,000 fine. MEDISCA and DOS SANTOS also forfeited and paid \$1,763,529, which represented MEDISCA's gross profits from the unlawful drug sales.

On October 14, 2011, MEDISCA and DOS SANTOS each pled guilty to the misdemeanor charge of introducing a misbranded drug, specifically somatropin, into interstate commerce using misleading labeling.

United States Attorney Hartunian said: "The U.S. Food and Drug Administration protects and promotes good health by ensuring that drugs are safe and effective. A safety review of recombinant human growth hormone (somatropin) by the FDA is ongoing. These circumstances underscore the importance of following and enforcing the rules. Circumventing them for financial gain increases the risk of illicit use and harm, and cannot be tolerated. We are committed to working with the FDA and other agencies to enforce vigorously the standards that protect public health and safety."

In entering their guilty pleas last October, DOS SANTOS and MEDISCA admitted that from approximately July 2004 through February 2007, MEDISCA had imported from China and distributed to pharmacies throughout the United States over 1737 grams of somatropin, also known as human growth hormone. They each also admitted that, from at least as early as March 4, 2005, MEDISCA provided promotional literature to the pharmacies claiming that the somatropin was either an FDA-approved drug or from an FDA-approved facility based on the fact that the Chinese manufacturer of the somatropin had obtained from FDA a National Drug Code number for the product. The promotional literature was signed by MEDISCA officers and either provided to MEDISCA sales representatives to distribute to the pharmacies or sent directly to the pharmacies by the MEDISCA officers. The National Drug Code is a number system FDA utilizes to assign a drug listing number to each drug or class of drugs a manufacturer lists and registers with the FDA. However, FDA's regulations explicitly state that "assignment of a NDC number does not in any way denote approval of the firm or its products," and "[a]ny representation that creates an impression of

official approval because of registration or possession of a registration number or NDC number is misleading and constitutes misbranding."

The case was investigated by the U.S. Food and Drug Administration, Office of Criminal Investigations, New York Field Office and was prosecuted by the United States Attorney's Office for the Northern District of New York and FDA's Office of Chief Counsel.

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