



# Department of Justice

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Northern District of New York

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## GUILTY PLEAS IN HUMAN GROWTH HORMONE DISTRIBUTION CASE

### **New York Corporation and its President Admit to Distributing Somatropin Using Misleading Claims**

ALBANY, NY - MEDISCA, INC., a New York corporation located in Plattsburgh, New York, and its President, ANTONIO DOS SANTOS, age 63, of Montreal, Canada, each have pled guilty to a one count misdemeanor of introducing a misbranded drug, specifically somatropin, into interstate commerce using misleading labeling, announced 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. The guilty plea was entered on Friday, October 14, 2011, in United States District Court in Albany, New York before United States Magistrate Judge David R. Homer. Sentencing is scheduled for March 14, 2012, at 1:30 p.m. in Albany, New York. DOS SANTOS faces a maximum term of up to one year in prison, a \$100,000 fine, and is subject to up to 1 year of supervised release to follow any period of incarceration, and an order of restitution. MEDISCA faces a maximum term of five years probation, a \$200,000 fine, and an order of restitution. In addition, DOS SANTOS and MEDISCA have agreed to forfeit over \$1.7 million, which represents MEDISCA's gross profits from the unlawful drug sales.

United States Attorney Hartunian stated: "FDA's oversight of pharmaceutical drugs is very important. When the FDA's regulatory scheme is circumvented, the risk of abuse is real. This office will continue to work closely with our law enforcement partners to aggressively combat this threat, and to prosecute those who use misleading claims to profit from the improper distribution of such substances."

In entering their guilty pleas, DOS SANTOS and MEDISCA admitted that from approximately July 2004 through February 2007, MEDISCA 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 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 was 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 is being prosecuted by the United States Attorney's Office for the Northern District of New York, Assistant U.S. Attorney Thomas A. Capezza and FDA's Office of Chief Counsel, Associate Chief Counsel Jason Hedges.

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