NEWS RELEASE

OFFICE OF THE UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF CALIFORNIA
San Diego, California

United States Attorney
Karen P. Hewitt

For Further Information, Contact: Assistant United States Attorney Melanie K. Pierson (619)557-5685

For Immediate Release

NEWS RELEASE SUMMARY - February 8, 2010

United States Attorney Karen P. Hewitt announced that James Folsom was sentenced today in federal court in San Diego to serve 51 months in custody and a $250,000 fine following his conviction on twenty-six felony counts relating to the sale of unapproved medical devices and the commission of offenses while on pretrial release. The Honorable John A. Houston, United States District Judge, also ordered the destruction of over 450 devices that had been seized by the government during the execution of a search warrant at a self-storage unit used by the defendant. A federal jury found Folsom guilty of conspiring to ship adulterated and misbranded Rife-type biofrequency devices in interstate commerce, following a two-week trial in 2009.

According to evidence presented at trial, the device, marketed by Folsom under the names "NatureTronics," "AstroPulse," "BioSolutions," "Energy Wellness," and "Global Wellness," consisted of a micro-current frequency generator with a digital readout, two stainless steel cylinders, two personal application plates with connectors, and lead wires connecting the device to the cylinders and the plates. Users were provided with an operating manual that set forth hundreds of digital settings for the device, directed to specific conditions from AIDS, diabetes, strokes, and ulcers to worms. Users were advised to connect the

cylinders or plates to the machine and touch them to the body for a recommended run time to treat each condition.

According to the testimony at trial, during the period from 1997 through August 2008, the defendant purchased over 9,000 units, which he sold to distributors for approximately $1000-1200, and to retail customers for $1995, with sales totaling over $8 million. The devices were manufactured by the defendant and others in a San Diego location, which he failed to register with the Food and Drug Administration (FDA) as a device manufacturing establishment. The defendant used the false name "Jim Anderson," when selling the device and used post office boxes, self-storage units, and bank accounts opened in the names of others to conduct his business in an effort to avoid detection by the FDA.

The devices were adulterated in that they were marketed without a valid investigational device exemption, without pre-market approval, and in violation of an electrical performance standard set by the FDA, prohibiting lead wires that come into contact with patients from being able to come in contact with potentially hazardous voltages. The devices were also misbranded in that they were marketed without valid clearance from the FDA, did not bear the name and address of the manufacturer on the labeling, and were produced in an unregistered manufacturing establishment.

United States Attorney Hewitt said, "The United States Attorney's Office will vigorously prosecute those who compromise or jeopardize public safety by selling misbranded or adulterated products."

"The FDA Office of Criminal Investigations is fully committed to investigating and supporting the prosecution of those who may endanger the public's health and safety by manufacturing and selling unsafe products to be used on an unsuspecting public. We continue to look forward to working with our law enforcement partners and commend the U.S. Attorney's Office for their diligence," said Thomas Emerick, Special Agent in Charge, FDA Office of Criminal Investigations, Los Angeles Field Office.

"The Postal Inspection Service remains committed to keeping our nation's mail system free from criminal misuse and we will continue to join forces with our law enforcement partners to protect the American public from fraud," stated B. Bernard Ferguson, Inspector in Charge of the Los Angeles Division.

DEFENDANT **Criminal Case No. 08CR1092-JAH**

James M. Folsom

SUMMARY OF CHARGES

Count 1

Conspiracy, in violation of Title 18, United States Code, Section 371

Counts 2-8, 21-23

Introduction of an Adulterated Device into Interstate Commerce, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 351(e) and (f)

Counts 9-15, 24-26

Introduction of a Misbranded Device into Interstate Commerce, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(o), 352(b) and 360(j) and (k);

Counts 16-20

Failure to Register a Device Establishment, in violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360

Commission of an Offense While on Pretrial Release, in violation of Title 18, United States Code, Section 3147.

AGENCIES

Food and Drug Administration, Office of Criminal Investigations
U.S. Postal Inspection Service