NEWS RELEASE

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

United States Attorney
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For Immediate Release

NEWS RELEASE SUMMARY - February 17, 2009

United States Attorney Karen P. Hewitt announced that James Folsom was found guilty by a federal jury earlier today in United States District Court in San Diego of twenty-six felony counts relating to his sale of an unapproved medical device. The verdict follows a two-week trial before the Honorable John A. Houston, United States District Judge.

According to evidence presented at trial, from 1997 through August 11, 2008, James Folsom conspired with others to ship adulterated and misbranded Rife-type biofrequency devices in interstate commerce. The device, sold 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, stroke, 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 testimony at trial, the defendant purchased over 9,000 units, which he sold to distributors for approximately $1000-1200 and to retail customers for $1995, with sales of 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, all in an effort to avoid detection by the FDA. The defendant also marketed his device "for investigational purposes," deceiving consumers into the false belief that he possessed a valid investigational device exemption from the FDA.

According to Assistant U.S. Attorney Melanie K. Pierson, who prosecuted the case, 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 is committed to the investigation of those who misuse our nation's mail system with total disregard for public health and safety. These scams target the most vulnerable, empty their

wallets, and give them nothing but false hope in return," said B. Bernard Ferguson, Inspector in Charge, Los Angeles Division of the U.S. Postal Inspection Service.

The jury also found that the defendant committed six of the offenses while on pretrial release on the charges in this case. As a result of this finding, the Court found that the defendant was not likely to obey the conditions of release as set, which specifically forbid him from selling or possessing the devices during the pendency of the case, and remanded him immediately into custody.

Sentencing is scheduled for May 11, 2009 at 10:30 a.m., before Judge Houston.

DEFENDANT **Criminal Case No. 08-CR-1092-JAH**

James M. Folsom

SUMMARY OF CHARGES

Count 1
Conspiracy, in violation of Title 18, United States Code, Section 371
Maximum Penalty: 5 years in custody and/or $250,000 fine

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)
Maximum Penalty: 3 years in custody and/or $10,000 fine per count

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)
Maximum Penalty: 3 years in custody and/or $10,000 fine per count

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
Maximum Penalty: 3 years in custody and/or $10,000 fine per count

Commission of an Offense While on Pretrial Release, in violation of Title 18, United States Code, Section 3147.
Provides for an additional penalty of 1 year in custody for Counts 7, 8, 14, 15 and 20
Provides for an additional penalty of 10 years in custody for Counts 21-26

AGENCIES

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