



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

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For Immediate Release

#### **NEWS RELEASE SUMMARY** - June 9, 2008

The United States Attorney's Office announced today that Michael J. Ellis, the founder and former president of San Diego-based corporation Metabolife International, Inc., was sentenced today by United States District Judge Napoleon A. Jones, Jr. to serve six months in custody and pay a fine of \$20,000. The sentence was imposed after Ellis pled guilty to the offense of making false statements to the Food and Drug Administration ("FDA").

According to court records, in April 1998 and February 1999, Ellis and his corporation sent letters to the FDA stating that Metabolife had "never received a notice from a consumer that any serious adverse health event has occurred because of the ingestion of Metabolife 356" and that Metabolife had a "claims - free history." Metabolife's own documents, however, demonstrated that Metabolife had received reports of seizures, heart attacks, strokes, losses of consciousness and other serious adverse health events -- often resulting in hospitalizations.

At the time Ellis and Metabolife submitted these false representations to the FDA, the FDA was considering whether to regulate ephedra products more stringently. In particular, in1997, the FDA proposed a rule that would have banned the sale of products containing 8 mg or more of ephedrine alkaloids and would have required stricter labeling of other ephedra supplements. The FDA's proposed rule would also have required that ephedra labels disclose the health risks of ephedra, such as heart attack, stroke, or death.

Metabolife was formerly one of the largest retailers of dietary supplements in the United States, based largely on sales of its ephedra-based product, Metabolife 356.

In 2002, however, Metabolife turned over reports of over 14,000 ephedra-related adverse events that the company had not previously released to the FDA. It was as a result of these reports and further investigation by both the FDA - Office of Criminal Investigations and the Internal Revenue Service - Criminal Investigation that on July 22, 2004, Ellis and Metabolife were indicted for making false statements to the FDA. The FDA ultimately banned ephedra-containing dietary supplements. On August 17, 2006, the Tenth Circuit Court of Appeals upheld the FDA's ban of ephedra, a ban that remains in effect.

In addition, following the indictment of Ellis and Metabolife, the FDA's ban on ephedra, falling sales, and numerous personal injury legal claims related to Metabolife 356, Metabolife filed for Chapter 11 bankruptcy in 2005.

### DEFENDANTS Case Number: 03 CR 1088-J

Michael J. Ellis

Metabolife International, Inc. San Diego, CA

#### SUMMARY OF CHARGES AND MAXIMUM PENALTIES

Title 18, United States Code, Section 1001 - Making False Statements to the Food and Drug Administration

## PARTICIPATING AGENCIES

Food and Drug Administration, Office of Criminal Investigation Internal Revenue Service, Criminal Investigation Division