

Update – June 2005 FTC Appeals Ruling

April 14, 2005 News Article on Ephedra Ban

WASHINGTON (Reuters) - U.S. health regulators failed to prove certain "low dose" ephedra supplements are unsafe, a U.S. court said in a ruling announced on Thursday that would allow some types of the controversial weight loss pill back on the market.

The U.S. Food and Drug Administration's decision to ban all ephedra dietary supplements -- regardless of dose -- until manufacturers could "demonstrate a benefit is contrary to the clear intent of Congress," the court said in its decision issued on Wednesday.

The ruling, which comes one year after FDA officials began a ban on the controversial weight loss pill, lifts the restriction for ephedra supplements with 10 milligrams or less of the active ingredient.

Nutraceutical International Corp. filed the suit challenging the agency's ban and posted the ruling on its Web site on Thursday.

An FDA spokeswoman said the agency was reviewing the ruling.

FDA officials have linked ephedra to death, heart attacks and strokes, but manufacturers say it is safe when used as directed.

Judge Tena Campbell of the U.S. District Court for the District of Utah said the FDA could not place the burden to prove safety on dietary supplement manufacturers as it does for drug and device makers.

Instead, the agency "must establish that (ephedra supplements) pose a significant or unreasonable risk by a preponderance of the evidence," Campbell wrote.