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Judge allows ban on ephedra nationwide

By Wayne Parry
 THE ASSOCIATED PRESS

NEWARK, N.J. — A federal judge allowed a nationwide ban on dietary supplements containing ephedra to take effect Monday, turning aside a request by two supplement makers.

U.S. District Judge Joel Pisano refused to grant a temporary restraining order sought by the two manufacturers that would have prevented the U.S. Food and Drug Administration from banning the products.

NVE Pharmaceuticals Inc. of Newton, the manufacturer of the popular diet supplement Stacker 2, had hoped to head off the nationwide ban on the herbal stimulant, arguing the main ingredient in its product is safe if used as directed.

The company had asked for the temporary restraining order pending further scientific tests. On Monday, a second company had been allowed to join the motion — the National Institute for Clinical Weight Loss, manufacturer of a product called Themalean.

Ephedra, once hugely popular for weight loss and bodybuilding, has been linked to 155 deaths and dozens more heart attacks and strokes.

After years of fighting manufacturers over ephedra's risks, the FDA announced in December that it was banning sales of the amphetamine-like herb — the first such ban of a dietary supplement. The ban takes effect Monday.

Research shows the herb can speed heart rate and constrict blood vessels even in seemingly healthy people, but it's particularly risky for those with heart disease or high blood pressure or who engage in strenuous exercise. Unlike medications, which must be proven safe and effective before they're allowed to be marketed, federal law allows dietary supplements to be marketed without such proof. To curb a supposed health risk, the law requires the FDA to prove it poses a significant health risk.

NVE Pharmaceuticals maintains that the FDA lacks proof that ephedra is dangerous. Its lawsuit argued the agency simply reacted to emotion of high-profile athletes like that of Baltimore Orioles pitcher Steve Bechler.

Ephedra ban goes into effect

A federal judge allowed a nationwide ban on dietary supplements containing ephedra to go into effect Monday despite a temporary restraining order sought by two manufacturers.

Ephedra, also known as Ephedrine, or Ma Huang

Properties and uses: Used to prevent attacks of bronchial asthma and to relieve nasal congestion. Common ingredient in weight loss products; shown to produce fat-loss and muscle gain in controlled tests.

Side effects: Raised blood pressure, can cause irregularities in heart rate, insomnia, tremors and headaches, seizures, heart attacks, strokes and death.

SOURCES: Food and Drug Administration; Harvard School of Public Health

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