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FDA ORDERED TO LIFT IMPORT BAN ON CHOLESTEROL AID

In a case that challenges the government's ability to regulate natural remedies, a federal judge ordered the Food and Drug Administration today to temporarily lift its ban on imports of a dietary supplement containing a cholesterol-reducing drug.

The chemical lovastatin occurs naturally in red yeast rice powder from China and the company that markets the powder under the name Cholestin had sought a preliminary injunction against the FDA.

In a three-page order late today, U.S. District Judge Dale Kimball said Pharmanex, which makes Cholestin, would suffer irreparable injury if the FDA's ban remained in place and issued the temporary injunction pending resolution of Pharmanex's lawsuit against the FDA.

He also found the company has "raised substantial and serious questions regarding the lawfulness of FDA's interpretation" of the 1994 Dietary Supplement Health and Education Act.

Kimball also defined Cholestin as a dietary supplement, not a drug that would be subject to FDA approval.

"The threatened injury to {Pharmanex} greatly outweighs whatever damage the proposed injunction may cause to defendants," Kimball wrote, pointing out that the FDA does not consider Cholestin dangerous.

The FDA could appeal and "will review the court order thoroughly, but at this time we anticipate we will continue to pursue the case on its merits," said spokeswoman Lorrie McHugh.

The injunction will allow Pharmanex to import 10 tons of red yeast rice to its Farmington, Utah, factory, which makes as many as 90,000 capsules a day. After that, the order allows the Simi Valley, Calif.-based company to import as much as six tons of the rice every three months.

Pharmanex said it was within five days of exhausting its supply of the powder, which contains, among other substances, lovastatin -- a natural version of a synthetic cholesterol-reducing drug that Merck & Co. sells under the brand name Mevacor.

Merck, based in Whitehouse Station, N.J., previously was reported as examining whether Cholestin violates Mevacor patents.

Pharmanex originally said it was targeting 58 million Americans with moderately high cholesterol levels. Most doctors would not prescribe cholesterol-reducing medication for those patients unless they had other risk factors. After the FDA considered that a drug claim, Pharmanex started advertising only that Cholestin promotes healthy cholesterol.

The dispute is the first challenge to the FDA's powers under the 1994 dietary supplement law.

The law provided for the widespread sale of herbs, teas and capsules containing ingredients that are not FDA-approved as safe and effective, but also set two major restrictions.

First, any FDA-approved drug ingredients cannot also be sold as dietary supplements unless they were sold as a supplement or food before the drug's approval. Second, supplement manufacturers may claim only general benefits for the ingredient, rather than cures, preventions or treatments of diseases.

FDA regulators say Cholestin runs afoul of the law on both counts: It was not sold as a supplement before Mevacor was approved, and Pharmanex has made improper claims about its effectiveness.

Comments