

# Food? Drug? The FDA says this capsule could cause deadly liver and lung problems

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After reports of "two serious and potentially life-threatening medical conditions," the FDA this week issued a consumer alert for osteoarthritis capsule Limbrel.

The alert: Don't take it.

And that came as a surprise to Limbrel manufacturer Primus Pharmaceuticals.

"They visited our offices on Nov. 8, as they said in the alert, then spent four days at our manufacturing facility," Primus executive director Mary Ann DeMarco said. "Nothing came of it and they closed the file as regards to manufacturing."

DeMarco said Limbrel, on the market since 2004, often is prescribed for patients who don't want to be on opioids.

The alert was issued Monday after Primus did not voluntarily recall the capsule. DeMarco said the company has no intention of doing so.

"Although the product is marketed as a medical food, the preliminary determination of the FDA investigation is that Limbrel is an unapproved new drug. The agency does not have mandatory recall authority over drug products," the alert states. "The FDA reminds consumers not to use Limbrel because of the risk of drug-induced liver injury, and a lung condition called hypersensitivity pneumonitis."

Those are the "life-threatening medical conditions" the FDA links to the capsule. DeMarco said Limbrel's only been connected with acute hypersensitivity pneumonitis, which isn't fatal, and patients were fine once removed from Limbrel. As for the [liver problems](#), she pointed to Limbrel's warning against combining it over-the-counter non-steroidal anti-inflammatory drugs.

"People pop Aleve like candy," DeMarco said. "It's hard to prove causality."

Osteoarthritis is, according to the Arthritis Foundation, "the most common chronic condition of the joints. It occurs when the cartilage or cushion between joints breaks down leading to pain, stiffness and swelling."

The FDA's alert says it's investigating a rise in "serious adverse events" among the 194 reports of health problems regarding Limbrel.

People who develop liver problems often suffer from jaundice, nausea, weariness and a temperamental stomach.

The American Lung Association says hypersensitivity pneumonitis is "a disease of the lungs in which your lungs become inflamed as an allergic reaction to inhaled dust, fungus, molds or chemicals." Symptoms include fever, chills, headache, cough, chronic bronchitis, shortness of breath or trouble breathing, weight loss, and fatigue.

Anyone who experiences health issues from taking Limbrel or any medical product can report it to the FDA.

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