Wyeth sues FDA to block rival generic antibiotic

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(AP) -- Drugmaker Wyeth on Wednesday sued the Food and Drug Administration to block the sale of a generic rival to its intravenous antibiotic Zosyn, claiming the generic is not an equivalent product and could harm critically ill patients.

Madison, N.J.-based Wyeth filed a federal lawsuit against the FDA, seeking both a temporary restraining order and a preliminary injunction. The lawsuit seeks to prevent Orchid Chemicals & Pharmaceuticals Ltd. of Chennai, India, from selling a generic version of Zosyn that the FDA approved last week.

Wyeth's head of global medical affairs, Joe Camardo, said patient safety is at stake and that Orchid's product could lead to preventable medical errors.

"Over 2 million people get Zosyn in any given year," Camardo told The Associated Press in an interview.

Many are critically ill patients with very serious infections, he said. So hospital workers are rushing to set up an intravenous line to rapidly feed in both Zosyn and, often, a standard IV solution to boost blood volume and maintain blood pressure. The problem is that with an older formulation of Zosyn, which Wyeth claims is what Orchid will be selling, if the same IV line is used, Zosyn can mix with the intravenous solution and cause a chemical reaction that inactivates the antibiotic, limiting how much patients would get.

"They wouldn't get the full dose," Camardo said.

That could mean the patient doesn't get enough antibiotic to stop the infection.

In addition, having two different versions of the same antibiotic on the market could cause confusion when hospital workers are rushing to save very ill patients, Camardo said.

The lawsuit calls the FDA's approval of Orchid's products "unlawful" and "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law." The approval "permits the marketing of a generic drug product that cannot be safely used in the same manner as the branded product" and "seriously endangers patient health," the lawsuit states.

Wyeth discontinued the old version in October 2005, when the FDA approved a newer version that adds two ingredients to prevent the harmful chemical reaction.

Zosyn has been on the U.S. market since 1993. Wyeth reported that sales of Zosyn and Tazocin, as it's called in other countries, last year totaled $1.3 billion.

Camardo said that Wyeth several years ago filed what's called a "citizen's petition" with the FDA, a request asking the agency not to allow generic Zosyn because of the potential for problems. The citizen's petition laid out Wyeth's scientific arguments and contained similar statements of support from outside experts on medication errors and drug interactions and effects, he said.

But the FBI denied the citizen's petition last Tuesday and then approved Orchid's drug last Wednesday, Camardo said.

FDA spokesman Christopher Kelly said the agency was looking into the lawsuit and would provide comment later.

Officials at Orchid's U.S. subsidiary, Orgenus Pharma Inc., did not immediately respond to messages seeking comment.

The lawsuit was filed in U.S. District Court in Washington, D.C.

The 33-page suit names as defendants the FDA, the U.S. Department of Health and Human Services and its head, Secretary Kathleen Sebelius, and Dr. Margaret Hamburg, commissioner of the FDA.

The suit requests action by the court within 10 days because Orchid has said it plans to launch its products "immediately," Camardo said.

Orchid, in operation since 1994, makes a number of generic drugs, particularly antibiotics, as well as active ingredients for medicines, and also does research on experimental drugs. It is one of India's top 15 pharmaceutical companies.

The company has FDA approval to sell generic Zosyn, known chemically as piperacillin and tazobactam, in multiple dosages. Orchid noted that as the first applicant to the FDA, it will have a 180-day exclusive period to sell generic versions in the U.S. It plans to market the drugs in partnership with another generic drugmaker, Apotex Inc.

In morning trading, Wyeth shares fell 20 cents to $48.34.