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Group Sues FDA Over Drug Linked to Liver Damage

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By Lisa Richwine

WASHINGTON (Reuters) - A U.S. consumer group on Monday sued the Food and Drug Administration in an effort to force a ban on a Bristol-Myers Squibb antidepressant linked to life-threatening liver damage.

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The group, Public Citizen, said it filed the suit because the FDA had failed to act on a petition filed more than a year ago to outlaw the drug, called Serzone.

Serzone has been pulled from the market in Europe and Canada and is slated to be withdrawn in Australia and New Zealand in May, Public Citizen said.

"It is grossly negligent for the FDA to allow doctors to continue to prescribe, and patients to continue to take, Serzone," Dr. Sidney Wolfe, head of Public Citizen's Health Research Group, said in a statement.

The group cited reports in an FDA database of 55 cases of liver failure among Serzone users, including 20 deaths. Because drug side effects typically are under-reported, the actual number of cases likely is higher, the group said.

Bristol-Myers spokesman Rob Hutchison said it would be inappropriate to comment on the lawsuit because it had been filed against the FDA, not the company.

In the past Bristol-Myers has defended Serzone as an important option for treating depression and said liver problems were rare.

FDA spokeswoman Susan Cruzan said the agency would review the lawsuit.

Since January 2002, Serzone's label has included a "black box" warning that it may cause life-threatening liver damage. The instructions urge doctors to tell patients to be alert for signs of liver problems.

Public Citizen petitioned for a ban on Serzone in March 2003.

In its lawsuit, Public Citizen asked the court to find the FDA's failure to act on the petition illegal, and to order the agency to make a decision.

The suit was filed in U.S. District Court for the District of Columbia.

Serzone has been a relatively minor drug for Bristol-Myers, even before generic competition debuted last fall. The drug's generic name is nefazodone.

Shares of New York-based Bristol-Myers, which earlier Monday revised its financial results again, fell 64 cents to close at \$25.19 on the New York Stock Exchange.

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