Watchdog group seeks FDA ban of antifungal tablets

February 24 2015

(AP)—A consumer safety group is calling on the Food and Drug Administration to pull certain antifungal tablets off the market, saying there are safer medicines that do not carry risks of liver damage.

Public Citizen filed a petition Tuesday asking the FDA to ban ketoconazole tablets, which are used against hard-to-treat fungal infections.

First approved in 1981, the drug has long carried a boxed warning about potentially fatal liver damage. In July 2013 the FDA restricted ketoconazole's use to infections that do not respond to other drugs. The agency also required that all patients filling a prescription receive a medication guide detailing the drug's risks.

But Public Citizen notes that European regulators went further, recommending that all oral versions of the drug be removed from the market. Additionally, the consumer watchdog group points to an internal FDA memo in which 14 scientists from the agency's surveillance unit conclude that ketoconazole's risks outweigh its benefits. Those findings were delivered at an agency workshop in January 2013, six months before the FDA decided to restrict the drug's use, but keep it on the market.

Last year U.S. patients filled 462,000 prescriptions for the drug, according to data cited by Public Citizen.

"Unless the FDA bans oral ketoconazole, its continued marketing will result in hundreds of preventable cases of serious liver damage a year," states the group's petition.

Ketoconazole is also available in topical formulations, though Public Citizen says those versions do not carry the risks cited in the petition.

Tablets of the drug are sold by generic drugmakers Teva Pharmaceuticals and Mylan Inc.