FDA requires strong amputation warning on sedative

16 September 2009, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Makers of injected promethazine, a sedative also used to treat nausea and vomiting, are being required to put the strongest warning possible on the product because it can cause tissue damage leading to amputation, the Food and Drug Administration said Wednesday.

The drug, previously sold by Wyeth Pharmaceuticals Inc. under the brand name Phenergan, was at the heart of a U.S. Supreme Court case this spring that ended in a ruling that consumers harmed by a medication approved by the FDA still have the right to sue the manufacturer.

Wyeth had appealed the case up to the Supreme Court after a Vermont woman named Diana Levine, who once played the guitar and piano professionally, sued because she had to have her right arm amputated after being injected with Phenergan. Levine's lawsuit, which claimed she wasn't sufficiently warned of the risks of using Phenergan, won her a $6.7 million jury award.

The FDA said Wednesday that makers of generic promethazine will have to put a "black box" warning at the top of the detailed package insert explaining that when the drug is administered incorrectly, it can damage skin severely, including causing gangrene.

The FDA said promethazine should be injected deep into muscle, never into an artery or under the skin and, when given intravenously, it should be done slowly and at a low concentration. That's because the drug can leach out of a vein and seriously damage surrounding tissue.

Companies will have 30 days to provide the FDA with acceptable wording for the package insert. Otherwise, the FDA can order changes it deems appropriate.

The warning, which already is in the package insert but not highlighted in a box outlined in black, also is being sent to doctors.

Promethazine has been on the market since 1956. FDA said reports and medical literature and reports the agency received about side effects from the drug showed it has been linked to an unspecified number of gangrene cases requiring amputation.

In a 6-3 decision in March, the Supreme Court rejected Wyeth's claim that federal approval of Phenergan and its warning label should have shielded the company from lawsuits like Levine's.

Prior to that, business groups had aggressively pushed for such limits on lawsuits through the doctrine of "pre-emption" - the idea that federal regulation trumps rules that might differ from state to state.

The Supreme Court had largely agreed, ruling in the prior term that FDA approval shields medical devices from most lawsuits.