FDA Orders Strong Antidepressant Warnings

By DIEDTRA HENDERSON, AP Science Writer

WASHINGTON - All antidepressants must carry a "black box" warning, the government's strongest safety alert, linking the drugs to increased suicidal thoughts and behavior among children and teens taking them, the Food and Drug Administration (news - web sites) said Friday.

Because the warnings are primarily seen by doctors, the agency also is creating a medication guide for patients to advise them of the risk.

Dr. Lester Crawford, acting FDA (news - web sites) commissioner, said the agency sought to balance the increased risk of suicidal thoughts and behavior against the known benefit of treating depression in children.

"We continue to believe, however, that these drugs provide significant benefits for pediatric patients when used appropriately," he said at a news conference.

He said the new labels warn of the "risk of suicidality and encourages prescribers to balance this risk with clinical need."

Prozac is the only antidepressant approved for use in children.

On average, 2 percent to 3 percent of children taking antidepressants have increased suicidal thoughts, independent experts, working with Columbia University, found.

The FDA announcement follows to the letter guidance from federal advisers. After searing and emotional public hearings one month ago, the advisers urged the agency to add its most strident warnings to the drugs.

The FDA said in a statement that it recognizes that depression in pediatric patients "can have significant consequences in pediatric patients if not appropriately treated. The new warning language recognizes this need but advises close monitoring of patients as a way of managing the risk of suicidality."

An information guide will be distributed with each antidepressant prescription. Parents will be advised to look for warning signs in children that include worsening depression, agitation, irritability, and unusual changes in behavior. Those worrisome signs could come within the first months of starting an antidepressant or when the drug's doses changes — higher or lower.

To make sure the medication guide is available with each prescription or refill, Crawford said the FDA would work with manufacturers to develop "unit of sale" packaging for all antidepressants. In "unit of sale" packaging, a medication is distributed in its original container and pre-labeled by the manufacturer. It contains sufficient medication for one normal course of therapy.

In 24 trials involving more than 4,400 patients taking antidepressants, researchers found a greater risk of increased suicidal thoughts and behavior during the first few months of treatment.

Celexa, Prozac and Zoloft posed lower risks for children, researchers found, while Luvox, Effexor and Paxil had higher risks of increased suicidal thoughts and behavior.

Prozac is the only antidepressant approved by the FDA for use for treating depression in pediatric patients.

Anafranil, Prozac, Luvox and Zoloft have been used for treating obsessive compulsive disorder in pediatric patients.

The new warnings, however, will be carried by all antidepressants, including Anafranil, Aventyl, Celexa, Cymbalta, Desyrel, Effexor, Elavil, Lexapro, , Ludiomil, Luvox, Marplan, Nardil, Norpramin, Pamelor, Parnate, Paxil, Pexeva, Prozac, Remeron, Sarafem, Serzone, Sinequan, Surmontil, Symbyax,Tofranil, Tofranil-PM, Triavil, Vivactil, Wellbutrin, Zoloft and Zyban.

The agency's action comes at a time when it faces withering criticism for not acting sooner on antidepressants, and for the shortage of flu vaccine and the high-profile withdrawal of Vioxx for safety concerns.

Congressional investigations have focused on allegations the agency silenced its own employees who tried to raise safety concerns on the antidepressants and Vioxx.