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ADHD Drug Makers to Warn of Side Effects

Government tells ADHD drug makers to warn patients of cardiovascular and mental risks

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WASHINGTON, Feb. 22, 2007

(AP) Drugs prescribed to treat attention deficit hyperactivity disorder will include guides to alert patients and parents of the risks of mental and heart problems, including sudden death.

The Food and Drug Administration said Wednesday that it directed the manufacturers of Ritalin, Adderall, Strattera and all other ADHD drugs to develop the guides. In May 2006, the agency told manufacturers to revise the labels of the drugs to reflect concerns about the cardiovascular and psychiatric problems.

Draft versions of the guides posted on the FDA Web site include discussion of reports of increased blood pressure and heart rate in ADHD patients, as well as cases of sudden death in some who have heart problems and heart defects. In adult patients, the reported problems also include stroke and heart attack.

The alerts also cover psychiatric problems, such as hearing voices, unfounded suspicions and manic behavior, of which there is a slightly increased risk in patients who take the drugs, the FDA said. The guides also tell patients and their parents of precautions they can take to guard against the risks.

Wednesday's announcement came roughly a year after two panels of FDA advisers recommended that the drugs include such patient medication guides. The announcement covers 15 drugs, including extended-release, patch and chewable versions of some of them.

Ritalin is manufactured by Novartis Pharmaceuticals Corp. and in generic form by other companies; Adderall is made by Shire Pharmaceuticals Inc.; Strattera by Eli Lilly & Co.

ADHD affects an estimated 3 percent to seven percent of school-age children and four percent of adults, the FDA said.

On the Net:

Food and Drug Administration ADHD drug information:
<http://www.fda.gov/cder/drug/infopage/ADHD/default.htm>

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