

## FDA News

### FOR IMMEDIATE RELEASE

P07-26

February 21, 2007

### Media Inquiries:

Sandy Walsh, 301-827-6242

### Consumer Inquiries:

888-INFO-FDA

## FDA Directs ADHD Drug Manufacturers to Notify Patients about Cardiovascular Adverse Events and Psychiatric Adverse Events

The U.S. Food and Drug Administration (FDA) today directed the manufacturers of all drug products approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) to develop Patient Medication Guides to alert patients to possible cardiovascular risks and risks of adverse psychiatric symptoms associated with the medicines, and to advise them of precautions that can be taken.

"Medicines approved for the treatment of ADHD have real benefits for many patients but they may have serious risks as well," said Steven Galson, M.D., MPH, Director, Center for Drug Evaluation and Research (CDER). "In our ongoing commitment to strengthen drug safety, FDA is working closely with manufacturers of all ADHD medicines to include important information in the product labeling and in developing new Patient Medication Guides to better inform doctors and patients about these concerns."

Patient Medication Guides are handouts given to patients, families and caregivers when a medicine is dispensed. The guides contain FDA-approved patient information that could help prevent serious adverse events. Patients being treated with ADHD products should read the information before taking the medication and talk to their doctors if they have any questions or concerns.

ADHD is a condition that affects approximately 3 percent to 7 percent of school-aged children and approximately 4 percent of adults. The three main symptoms are inattention, hyperactivity, and impulsivity. People with ADHD may have difficulty in school, troubled relationships with family and peers, and low self-esteem.

An FDA review of reports of serious cardiovascular adverse events in patients taking usual doses of ADHD products revealed reports of sudden death in patients with underlying serious heart problems or defects, and reports of stroke and heart attack in adults with certain risk factors.

Another FDA review of ADHD medicines revealed a slight increased risk (about 1 per 1,000) for drug-related psychiatric adverse events, such as hearing voices, becoming suspicious for no reason, or becoming manic, even in patients who did not have previous psychiatric problems.

FDA recommends that children, adolescents, or adults who are being considered for treatment with ADHD drug products work with their physician or other health care professional to develop a treatment plan that includes a careful health history and evaluation of current status, particularly for cardiovascular and psychiatric problems (including assessment for a family history of such problems).

As part of the Agency's ongoing regulatory activity, in May 2006 the FDA directed manufacturers of these products to revise product labeling for doctors to reflect concerns about adverse cardiovascular and psychiatric events. These changes were based on recommendations from the FDA Pediatric Advisory Committee and the Drug Safety and Risk Management Advisory Committee. To help patients understand these risks, an additional part of this revised labeling process is the creation of a Patient Medication Guide for each individual product.

The medicines that are the focus of the revised labeling and new Patient Medication Guides include the following 15 products:

- Adderall (mixed salts of a single entity amphetamine product) Tablets
- Adderall XR (mixed salts of a single entity amphetamine product) Extended-Release Capsules
- Concerta (methylphenidate hydrochloride) Extended-Release Tablets
- Daytrana (methylphenidate) Transdermal System
- Desoxyn (methamphetamine HCl) Tablets
- Dexedrine (dextroamphetamine sulfate) Spansule Capsules and Tablets

- Focalin (dexamethylphenidate hydrochloride) Tablets
- Focalin XR (dexamethylphenidate hydrochloride) Extended-Release Capsules
- Metadate CD (methylphenidate hydrochloride) Extended-Release Capsules
- Methylin (methylphenidate hydrochloride) Oral Solution
- Methylin (methylphenidate hydrochloride) Chewable Tablets
- Ritalin (methylphenidate hydrochloride) Tablets
- Ritalin SR (methylphenidate hydrochloride) Sustained-Release Tablets
- Ritalin LA (methylphenidate hydrochloride) Extended-Release Capsules
- Strattera (atomoxetine HCl) Capsules

The draft Patient Medication Guides for each product can be found at <http://www.fda.gov/cder/drug/infopage/ADHD/default.htm>. For more information please visit [www.fda.gov](http://www.fda.gov).

####

[RSS Feed for FDA News Releases](#) [\[what's this?\]](#)

---

[Get free weekly updates](#) about FDA press releases, recalls, speeches, testimony and more.

---

[FDA Newsroom](#)

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)