

- [Home Page](#)

ADHD drugs to carry warnings regarding heart problems, psychotic behavior and sudden death

Pharmaceutical News

Published: Thursday, 24-Aug-2006

 [Printer Friendly](#)  [Email to a Friend](#)

According to U.S. health officials several drugs used to treat attention deficit hyperactivity disorder (ADHD) must now include new warning information about the risk of serious heart problems, psychotic behavior and sudden death.

The [Food and Drug Administration](#) says the drugs which include Dexedrine (Glaxo) and Ritalin (Novartis) are stimulants that can raise blood pressure, and must also include warnings about the risk of behavioral problems such as aggression and mania.

Dexedrine will also include warnings about the risk of sudden death, hypertension and other concerns associated with stimulant treatment in children and adolescents who have heart problems.

It is unclear at this stage whether other ADHD drugs such as Concerta (Johnson & Johnson) and Strattera (Eli Lilly) also must carry the warnings.

Strattera already carries a caution about suicidal thoughts, while Adderall (Shire) already carries a warning that misuse can cause heart problems.

The FDA's decision comes months after two separate panels of outside experts offered conflicting opinions on whether the risks warranted the strongest warnings possible, a black box warning.

It was in March that FDA advisers said new information about the risks should be added to the labels for attention deficit drugs but the panel of independent experts stopped short of supporting a boxed warning.

They expressed concern that new warnings could discourage the use of the medicines, which the FDA has estimated see about 1 million prescriptions for adults and 2 million for children each month.

But critics say many of the prescriptions are unnecessary and that the drugs are over used.

A different FDA panel in February had recommended black box heart-related warnings but said it was unclear if the drugs caused heart-related complications.

Canadian health authorities have also publicly warned people with high blood pressure, heart disease and other medical problems to avoid taking medications for ADHD.