

August 22, 2006

## F.D.A. Strengthens Warnings on Stimulants

By [GARDINER HARRIS](#)

WASHINGTON, Aug. 21 — Federal drug regulators have ordered that strong warnings be put on the labels of stimulants like Ritalin to caution against their use in adults or children with heart problems and to alert doctors that the drugs cause one child in a thousand to experience hallucinations.

The new warnings are not as strong as those approved in February by an advisory committee for the [Food and Drug Administration](#), but they significantly strengthen the risk information already on the drugs.

“We’re not trying to scare people out of using these drugs,” said Dr. Robert J. Temple, director of the Office of Medical Policy at the drug agency. “Still, I would be extremely reluctant to put people with heart failure on one of these drugs.”

The warnings come after scattered reports of children dying suddenly while taking the drugs. In some cases, the children were later determined to have had structural defects of the heart.

The new warnings advise against giving such children stimulants. But structural heart problems often go undiagnosed because the tests needed to find them can be expensive.

“The difficulty for parents is that doctors won’t do a thousand-dollar heart work-up for every kid,” Dr. Temple said. “The message here, though, is that you have to do your best to find these problems out. Listen for murmurs.”

The new warnings state in part, “Sudden deaths, strokes and myocardial infarction have been reported in adults taking stimulant drugs at usual doses.”

The warnings will be put on Adderall and Concerta as well as Ritalin.

At a meeting in February, an F.D.A. advisory committee focused attention on stimulants’ risks in adults after a report suggested that the drugs might double the risk of strokes and serious arrhythmias. Such an increase may not be significant in children, whose heart risks are low, but it could cause concern in adults, committee members said.

Dr. Steven E. Nissen, chairman of the cardiology department at the Cleveland Clinic Foundation and a member of the February committee, said in an interview that he was pleased with the drug agency’s action. “I think this goes a long way,” Dr. Nissen said, “toward properly warning physicians and patients of the potential cardio and psychiatric risks of these drugs.”

Nearly four million people take stimulants to treat attention deficit disorder and hyperactivity. Ritalin has

been marketed since 1955, and dozens of studies have shown it to be safe and effective. But no studies have been of sufficient duration or included enough participants to evaluate stimulants' long-term effects on the heart.

Dr. Temple said the F.D.A. was exploring ways to study the problem.

Copyright 2006 The New York Times Company

[Privacy Policy](#) | [Search](#) | [Corrections](#) | [RSS](#) | [First Look](#) | [Help](#) | [Contact Us](#) | [Work for Us](#) | [Site Map](#)

---