



INFORMATION SHEET SAFETY OF PILLS FOR TREATING ADHD

Q: What has the FDA learned about the safety of pills to treat ADHD?

A: The Food and Drug Administration (FDA) regularly gathers new information about approved pills for ADHD, called stimulants. They collect reports from doctors who notice something new about the health of their patients while taking the pills. Then the FDA asks expert doctors to go over these reports. Recently, reports about ADHD pills with brand names such as Ritalin, Concerta, Focalin, Adderall, and Metadate were reviewed. The reports showed that in the past few years, 25 patients (19 who were 18 years and younger) taking stimulants had suddenly died. In addition, 54 more patients on these pills had unusual heartbeats, heart attacks, or strokes. Some of the patients in these reports had heart problems before taking the ADHD pills. Some were taking other pills, so it is not clear which pills, if any, may have caused the problems.

On February 9, 2006, the FDA asked a group of doctors to help design new studies to find out if the ADHD pills caused these heart problems. Instead, the doctors recommended that the FDA put information about the heart risks of ADHD pills in each container of ADHD pills. They also recommended that the FDA include a warning, called a "Black Box" warning, in the pill's instructions.

Q: What does the FDA plan to do?

A: The FDA will ask another group of experts made up of doctors who care for children to look at the safety of ADHD pills. They may decide that no new action is needed. Or they may decide to recommend more studies or more information in the label. The FDA will carefully consider the recommendation of these experts.

Q: Are these safety reports about heart problems new?

A: No, they were first announced last year. They led to the withdrawal of one brand of the pills in Canada. After further review of the pill's safety, the Canadian government later put this same pill back on the market.

Q: What should doctors treating children with ADHD do?

A: Until more information is available, experts from AAP are advising doctors to continue their current practice. This includes an exam and careful diagnosis. There are many treatment options that may or may not include pills.

Q: What if my child is taking ADHD pills? Or what if I am considering this treatment for my child?

A: Talk with your child's doctor. Ask about the benefits and risks of taking pills to treat ADHD as well as the benefits and risks of not taking ADHD pills. Also, ask about non-pill treatments.

If you have more questions, please ask your child's doctor.

"Frequently Asked Questions" (FAQs) are from the American Academy of Pediatrics (AAP) (Posted: May 26, 2006).