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Naproxen Linked to Heart Disease, FDA Issues Warning

The US Food and Drug Administration (FDA) has issued a warning to users of the over-the-counter pain reliever Naproxen Monday after federal researchers found an increased number of heart attacks and strokes among users. According to stories in the December 21, 2004 CNN.com and the Medscape Medical news of the same date, Naproxen is the latest of the nonsteroidal anti-inflammatory drugs (NSAIDs) that have now been linked to an increase in cardiovascular problems.

This latest warning came after a study sponsored by the National Institute on Aging testing whether Celebrex or Naproxen would reduce the risk of Alzheimer's disease was halted when researchers noted a 50% greater incidence in heart attacks and strokes among participants who were taking Naproxen.

Because of this the FDA now urged users to contact their doctors and to avoid taking the drug for longer than 10 days. Helmut Schdefers, a spokesman for Bayer Healthcare AG, stated, "We are in agreement with FDA regulators that people taking Aleve should consult their doctors and avoid taking the drug for more than 10 days. Aleve is particularly disturbing because it's an over-the-counter drug."

David Graham, FDA drug safety researcher and whistleblower, told CNN, "Over-the-counter drugs are supposed to be the ones that are the absolutely safest." Graham then questioned the FDA by saying, "I think this asks the larger question, 'Why has FDA not done the job it needs to do to protect America from unsafe drugs?' " Graham said in his 20 years at the FDA, "safety has been at the back of the bus, if it's on the bus at all."

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