

FDA Panel Recommends Withdrawal of Acetaminophen-Containing Narcotics

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ROCKVILLE, Md -- July 1, 2009 -- The US Food and Drug Administration (FDA) held a public advisory committee meeting on June 29 and June 30, 2009 to discuss acetaminophen use in both over-the-counter (OTC) and prescription (Rx) products, the potential for liver injury, and potential interventions to reduce the incidence of liver injury.

The FDA advisory panel voted 20 to 17 that prescription products combining the ingredient with stronger narcotics should be pulled from the market. In addition, if the products remain on the market, the experts voted 36 to 1 that the US regulator should require boxed warnings on the drugs' labels.

Among the data presented at the meeting, panellists cited FDA figures indicating that 60% of acetaminophen-related deaths are associated with the use of prescription products.

Drugs to treat pain that combine acetaminophen with other narcotics include hydrocodone/acetaminophen (Vicodin) and oxycodone/acetaminophen (Percocet).

The FDA recognises that acetaminophen is an important drug used to treat pain and fever in both OTC and RX products and is not seeking to remove it from the market.

The risk of developing liver injury to the individual patient who uses the drug according to directions is very low.

However, acetaminophen containing products are used extensively making the absolute number of liver injury cases a public health concern.

The Drug Safety and Risk Management Advisory Committee with the Anesthetic and Life Support Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee provided the FDA with independent advice from outside experts.

These recommendations are advisory in nature and the FDA is not bound to follow their recommendations.

At this time, the FDA has not made any decisions regarding acetaminophen containing products, but is reviewing the recommendations of the advisory committee, all available safety and efficacy data as well as public input before making a final decision.

SOURCE: US Food and Drug Administration