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Canada Regulators Order ADD Drug Withdrawn

By THE ASSOCIATED PRESS

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TORONTO (AP) -- Canadian regulators ordered a drug for attention deficit hyperactivity disorder off the market late Wednesday because of reports that it has been linked to 20 sudden deaths and a dozen strokes, including some among children.

The U.S. Food and Drug Administration, however, said it had evaluated the same reports and doesn't believe the data warranted such action in the United States. In a statement late Wednesday, Health Canada said it is asking makers of related stimulants used to treat the commonly diagnosed condition to provide a thorough review of their worldwide safety data.

None of the deaths or strokes associated with Adderall XR were reported in Canada, department spokesman Ryan Baker said.

``However, Health Canada has received eight reports of adverse reactions ranging in severity from convulsions to minor skin rash,'' Baker said. ``It's not been determined yet whether these reactions were a result of Adderall XR use.''

Of the 20 cases of sudden death linked to the drug, 14 were in children. Two of the 12 strokes were suffered by children taking the drug. The adverse reactions were not associated with overdose, misuse or abuse of the drug, the department said.

The drug is made by Shire Pharmaceuticals Group PLC, based in Basingstoke, England, and is sold in Canada and the United States. A related immediate-release form of the drug, sold simply as Adderall, is sold in the United States but has not been approved for sale in Canada, where 11,000 patients are prescribed Adderall XR. Canadian officials approved that drug in January 2004.

Shire's chief executive, Matthew Emmens, said in a statement late Wednesday that the company ``remains confident in the safety and efficacy'' of the drug.

Emmens said the FDA had reviewed the same data as Health Canada last year and sought an additional warning in September that the drug should not be prescribed for people with ``structural cardiovascular abnormalities.''

About 700,000 people take Adderall XR in the United States, with about 300,000 more using Adderall, Shire spokesman Matthew Cabrey said Wednesday. Shire reported $140 million in U.S. sales of the drugs in the third quarter of 2004.

In a statement posted on its Web site late Wednesday, the FDA said it ``does not feel that any

immediate changes are warranted in the FDA labeling or approved use of this drug based upon its preliminary understanding of Health Canada's analyses of adverse event reports and FDA's own knowledge and assessment of the reports received by the agency."

Health Canada is asking people taking the drug or parents of children on it to consult their physicians immediately to select alternatives. It is also asking them not to discard unused pills but rather to take them to a pharmacy for safe disposal.

People taking related drugs for the management of ADHD should not stop their treatment but could consult their doctors if they have concerns, the department said.

In light of the international reports of adverse reactions, the department reviewed the drug's safety data and conducted a preliminary review of safety data for the other related stimulants authorized for treatment of ADHD in Canada.

The incidence of serious adverse reactions leading to death was higher in Adderall and Adderall XR combined than in any other drugs of the class, the release said.

ADHD is the most commonly diagnosed psychiatric disorder among school-aged children.