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HEALTH CANADA WITHDRAWS ADDERALL XR® FROM MARKET

WINNIPEG, February 9th, 2005 – Health Canada has made the decision to withdraw Adderall XR® from the Canadian market. The drug was indicated for use in the treatment of Attention Deficit Hyperactivity Disorders (ADHD) in children. This withdrawal follows safety information concerning the association of sudden deaths, heart-related deaths, and strokes in children and adults taking usual recommended doses of Adderall XR®.

Health Canada is advising patients who are currently being treated with Adderall XR® to consult their physician immediately about use of the drug, and selecting an appropriate treatment alternative.

The decision made by Health Canada comes as a result of a review of safety information provided by the manufacturer, Shire BioChem Inc., which indicated that there were 20 international reports of sudden death in patients taking either Adderall® (which was sold in the United States but not Canada) or Adderall XR® (sold in Canada). Fourteen deaths occurred in children and six deaths in adults. There were 12 reports of stroke, two of which occurred in children. However, none of the reported deaths or strokes occurred in Canada.

Health Canada has asked manufacturers of related stimulant products approved for the treatment of ADHD to provide a review of their worldwide safety data. Patients taking drugs of the same class for the management of ADHD should not discontinue their medication.

Adderall XR® was approved in Canada on January 23, 2004 for the management of ADHD in children.