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Department of Health and Human Services

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FDA Public Health Advisory: Safety of Vioxx

Merck & Co., Inc. today announced a voluntary withdrawal of Vioxx from the U.S. market due to safety concerns. Vioxx is a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) that was approved by FDA in May 1999 for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. It is also approved for the relief of the signs and symptoms of rheumatoid arthritis in adults and children.

The Agency was informed by Merck & Co., Inc. on September 27, 2004, that the Data Safety Monitoring Board for an ongoing long-term study of Vioxx (APPROVe) had recommended that the study be stopped early for safety reasons. The study was being conducted in patients at risk for developing recurrent colon polyps. The study showed an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx compared to placebo, particularly those who had been taking the drug for longer than 18 months. Based on this new safety information, Merck and FDA officials met the next day, September 28, 2004, and during that meeting FDA was informed that Merck was voluntarily withdrawing Vioxx from the market place.

The risk that an individual patient taking Vioxx will suffer a heart attack or stroke related to the drug is very small. Patients who are currently taking Vioxx should contact their physician for guidance regarding discontinuation and alternative therapies.

FDA is working closely with Merck to coordinate the withdrawal of this product from the U.S. market place. Healthcare professionals are advised to contact Merck at 1-888-368-4699 or at www.merck.com or at the FDA's Drug Information Office at 301-827-4573 or 1-888-463-6332 or go to Vioxx Information on FDA's website at: www.fda.gov/cder/drug/infopage/vioxx/default.gov for questions about this product.

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