FDA statement on Pfizer recall

Administration asks drug maker to pull arthritis painkiller Bextra from the market.

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NEW YORK (CNN/Money) - Pfizer Inc. said Thursday that the Food and Drug Administration asked it to pull its arthritis painkiller Bextra from the market. The following is from the FDA statement:

FDA has asked Pfizer, Inc. to withdraw Bextra (valdexocib) from the market because the overall risk versus benefit profile for the drug is unfavorable. FDA has also asked Pfizer to include a boxed warning in the Celebrex (celecoxib) label.

Pfizer has agreed to suspend sales and marketing of Bextra in the U.S., pending further discussions with the agency. Pfizer has agreed to work with FDA on the boxed warning for Celebrex.

FDA is asking manufacturers of all other prescription NSAIDs to revise their labels to include the same boxed warning highlighting the potential for increased risk of cardiovascular (CV) events and gastrointestinal (GI) bleeding associated with their use. Manufacturers of Celebrex and all other prescription NSAIDs will be asked to revise their labeling to include a Medication Guide for patients to help make them aware of the potential for CV and GI adverse events associated with the use of this class of drugs.

In addition, FDA is asking the manufacturers of all OTC NSAIDs to revise their labels to include more specific information about the potential CV and GI risks, and information to assist consumers in the safe use of the drugs. FDA is also asking manufacturers of OTC NSAIDs to include a warning about potential skin reactions. The labeling of the prescription NSAIDs already addresses potential skin reactions.

This current reexamination of the CV risks of NSAIDs began after Merck conducted a voluntary worldwide withdrawal of its COX-2 selective NSAID, Vioxx (rofecoxib), in September 2004. FDA will carefully review any proposal from Merck for resumption of marketing of Vioxx.

These actions are based on the available scientific data, including data accumulated since the drugs were approved. The FDA has carefully considered the presentations, discussions, and recommendations from the joint meeting of the Agency's Arthritis and Drug Safety and Risk Management Advisory Committee held on February 16-18, 2005.

To inform the public and healthcare community of its decisions, FDA today issued a Public Health Advisory (PHA) and updated patient and healthcare practitioner fact sheets.

Additional information about today's announcements is available on FDA's Web site at www.fda.gov/cder. Information can also be obtained by calling 1-888-INFO-FDA (888-463-6332).