

*American Academy of Orthopaedic Surgeons*

**Patient Safety**

**Member Alert**

**FDA issues public health advisory:  
Pfizer agrees to suspend sales of Bextra;  
New labeling for Cox-2, NSAIDs**

Today, April 7, 2005, the U.S. Food and Drug Administration (FDA) announced a series of changes on the marketing of all nonsteroidal anti-inflammatory drugs (NSAIDs), including Cox-2 inhibitors, prescription and over-the-counter (OTC) NSAIDs. In addition, the FDA has requested that Pfizer, Inc., withdraw Bextra (valdecoxib) from the market, based on an unfavorable risk/benefit profile. Pfizer has agreed to suspend worldwide sales of Bextra pending further discussions with the agency. Patients who are currently taking Bextra are urged to contact their physicians to consider alternative treatments.

The FDA has concluded that the benefits of Celebrex (celecoxib) outweigh the potential risks in properly selected and informed patients, and will allow it to remain on the market. However, the FDA has requested that the Celebrex label be revised to include a boxed warning about cardiovascular (CV) and gastrointestinal (GI) risks and specific information on the controlled clinical trial data that demonstrate an increased risk of adverse CV events with celecoxib. The FDA encourages health care providers to recommend the lowest effective dose for the shortest duration consistent with individual patient treatment goals. The FDA is also requiring that a Medication Guide be included and distributed to patients when the drug is dispensed.

The FDA is requesting that manufacturers of all prescription nonselective NSAIDs revise product labeling to include a boxed warning about CV and GI adverse events associated with the use of this class of drugs, a contraindication for patients who have recently undergone coronary artery bypass surgery and a Medication Guide for patients.

“Black box” warnings are the FDA’s most stringent level of warning alert on prescription medications and effectively deter manufacturers from producing direct-to-consumer advertising.

The FDA is asking manufacturers of many OTC NSAIDs, including ibuprofen, naproxen and meloxicam, to revise their labeling to include more specific information about potential CV and GI risks; instructions about which patients should seek advice from a physician before using these drugs; stronger reminders about limiting the dose and duration of treatment; and a warning about potential skin reactions.

These actions are based on available scientific data, including data accumulated since the drugs were approved. The FDA also carefully considered documents, presentations and recommendations from the joint meeting of its Arthritis and Drug Safety and Risk Management Advisory Committees held in February 2005.

AAOS members and other health care professionals should direct any questions to the FDA at 1-888-INFO-FDA (1-888-463-6332) or visit the agency's Web site at: <http://www.fda.gov/cder/drug/advisory/COX2.htm>

**American Academy of Orthopaedic Surgeons**  
**6300 N. River Road**  
**Rosemont, IL 60018**  
**(847) 823-7186**