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**FDA APPROVES NEW USE FOR PFIZER'S CELEBREX;  
FINALIZES PRESCRIBING INFORMATION, INCLUDING EXPECTED WARNINGS,  
FOR ALL SIX APPROVED USES**

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***Patients with Ankylosing Spondylitis, a Debilitating Form of  
Arthritis, Now Have New Treatment Option with Celebrex***

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***Celebrex Label Update Contains Cardiovascular  
and Gastrointestinal Warnings***

NEW YORK, Aug. 1 - Pfizer Inc said today that the U.S. Food and Drug Administration has approved the company's selective COX-2 inhibitor Celebrex (celecoxib) for the relief of the signs and symptoms associated with ankylosing spondylitis, a form of arthritis that affects the spine. Celebrex continues to be an important treatment option for patients suffering from the pain of osteoarthritis and adult rheumatoid arthritis, acute pain, menstrual pain, and as a treatment for familial adenomatous polyposis, a rare condition that leads to colon cancer.

Pfizer has accumulated extensive clinical data relating to Celebrex over the past ten years involving more than 40,000 patients worldwide. As expected, the FDA also finalized the prescribing instructions, or label, for Celebrex for all approved uses, including additional warnings about potential cardiovascular and gastrointestinal risks. The FDA also will require similar warnings for other older arthritis treatments like ibuprofen and naproxen.

Ankylosing spondylitis, which affects over 400,000 Americans, becomes the sixth approved indication for Celebrex in the United States. Unlike other forms of arthritis that typically affect older people, ankylosing spondylitis usually strikes between the ages of 17 and 35. Approximately as common as rheumatoid arthritis, ankylosing spondylitis also can cause inflammation, pain and stiffness in other areas of the body such as the shoulders, knees, hips, ribs, and feet.

"With this new indication, Celebrex offers physicians a new treatment option for this difficult-to-treat patient population," said Dr. Joseph Feczko, Pfizer's chief medical officer. "The inflammation associated with ankylosing spondylitis can cause such severe pain that people who suffer from this condition - often young men - cannot perform even simple, everyday activities like walking and may have trouble attending school or work."

As anticipated, the final label contains a boxed warning of potential cardiovascular and gastrointestinal risks for Celebrex that will be consistent with warnings for other prescription pain relievers, including older, commonly used medicines like ibuprofen and naproxen. This addition follows a February 2005 meeting of an FDA advisory panel, which conducted a rigorous scientific review of selective and non-selective pain relievers. The panel recommended that stronger warnings be added to all selective COX-2 pain medicines as well as to the older, non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen. In addition, the panel recommended avoiding usage of all NSAIDs and Cox-2 selective medicines to treat the acute pain associated with heart by-pass surgery.

"We have worked closely with the FDA to ensure that Celebrex's label provides physicians and patients with the information they

need to make the most appropriate and most informed treatment decisions," Dr. Feczko said.

The label recommends that Celebrex be prescribed at the lowest effective dose for the shortest duration consistent with individual patient treatment goals. "This is consistent with good medical practice with any medicine," Dr. Feczko said. The recommended dose for Celebrex is 200 mg daily for osteoarthritis and 200 mg to 400 mg daily for adult rheumatoid arthritis. For the management of the signs and symptoms of ankylosing spondylitis, the recommended dose of Celebrex is 200 mg daily in single or divided twice per day doses. If no effect is seen after six weeks, a trial of 400 mg daily may be worthwhile. If no effect is observed after six weeks on 400 mg daily, a response is not likely and consideration should be given to alternate treatment options. The approved dose for the prevention of intestinal polyps associated with familial adenomatous polyposis is 800 mg daily.

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*Additional Information About Celebrex:*

Celebrex may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Celebrex is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery.

NSAIDs, including Celebrex, cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration,

and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

As with all NSAIDs, Celebrex can lead to the onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. NSAIDs should be used with caution in patients with hypertension.

Celebrex is a sulfonamide and can cause serious skin adverse events, which can be fatal. These serious events can occur without warning and in patients without prior known sulfa allergy.

The most common side effects in arthritis trials were dyspepsia, diarrhea, and abdominal pain, and were generally mild to moderate. The types of adverse events reported in the ankylosing spondylitis studies were similar to those reported in the arthritis studies.

For complete prescribing information, please see [www.celebrex.com](http://www.celebrex.com).