

February 4, 2005

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: 2004 N-0559 – Overall Benefit to Risk
Considerations for Cox-2 Selective
Nonsteroidal Anti-inflammatory Drugs
Related Agents**

To Whom It May Concern:

We wish to express our concern about the availability of Cox-2 inhibitor, Celebrex, which is the only FDA approved treatment for the prevention of polyps in Familial Adenomatous Polyposis (FAP). FAP is an inherited rare “orphan disease” affecting very few people in the United States.

We understand the debate about the cardiovascular risks of Cox-2 inhibitors for osteoarthritis, and we encourage complete scientific analysis of the many Cox-2 clinical trials so that physicians and patients will be informed about the probability of risks. However, people with arthritis have many other treatment options for management of pain while people with FAP have a life-threatening disease with no other treatment options aside from Celebrex. Thus people who have been diagnosed with FAP are likely to accept higher risks in order to attain benefits from Celebrex, as long as they are properly informed about the risks.

The National Organization for Rare Disorders (NORD) is a federation of voluntary health organizations and individuals dedicated to helping people with rare “orphan” diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and service.

Celebrex has been shown to prevent the growth of polyps in people with familial adenomatous polyposis. The polyps are malignant and cause early death. Because Celebrex is the only FDA approved treatment for FAP, we hope you will ensure continued availability of Celebrex on the American market.

Sincerely,

Abbey S. Meyers
President
National Organization for Rare Disorders (NORD)
P.O. Box 1968
Danbury, CT 06813-1968
Phone: 203-744-0100
Fax: 203-798-2757
meyersa7@rarediseases.org
www.rarediseases.org