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

**RE: Docket 77N-0941 - Tentative Final Monograph for Internal Analgesic, Antipyretic and Antirheumatic Drug Products for OTC Use**

Dear Sir/Madam:

Attached, please find a recent paper by Fries and Bruce entitled, "Rates of serious gastrointestinal events from low dose use of acetylsalicylic acid, acetaminophen, and ibuprofen in patients with osteoarthritis and rheumatoid arthritis", appearing in the Journal of Rheumatology in October 2003, volume 30, number 10, pages 2226-2233. We are providing this paper to bring it to your attention.

In this prospective observational study, the prevalence of serious gastrointestinal (GI) events in patients taking intermittent or low doses of aspirin, acetaminophen or ibuprofen was examined. The study included 5692 patients with rheumatoid arthritis and 3124 patients with osteoarthritis. As lower doses of study analgesics were taken, serious GI events tended to be less prevalent. In patients taking a study analgesic alone, without other analgesics or corticosteroids, only one event occurred in over 900 patient-years of exposure. Of note, in over-the-counter doses, there were no significant differences in GI toxicity among the three analgesics.

If you have comments or questions, please contact the undersigned at 973 660-5753 or Barbara Wolfe at 973 660-6265.

Sincerely,  
WYETH CONSUMER HEALTHCARE  
*Barbara Wolfe* for

Sharon C. Heddish  
Vice-President, Regulatory Affairs

**77N-0941**

**SUP 1**