CHPA President Linda A. Suydam, D.P.A.
Oral Presentation

FDA Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee

February 17, 2005

Good afternoon and thank you for the opportunity to present an over-the-counter (OTC) manufacturers' perspective on the safety of nonsteroidal anti-inflammatory drugs (NSAIDs). The Consumer Healthcare Products Association (CHPA) is the 124-year-old national trade association representing manufacturers and distributors of OTC medicines. Our members account for more than 90 percent of OTC medicines sold at retail outlets. CHPA has a long history of working with FDA on important safety issues concerning OTC products.

In considering the safety of NSAIDs, the use of OTC NSAIDs should be clearly distinguished from long-term or chronic prescription NSAID use. OTC NSAIDs are used at lower doses, are not intended to be used on a chronic basis unless directed by a physician, and are used for mild, self-limiting conditions. Thus, OTC medicines have a different overall benefit-to-risk equation and a wider margin of safety than prescription NSAIDs.

OTC medicines also differ from prescription drugs in one other important aspect: The OTC Drug Facts label contains all of the information consumers need to decide if the medicine is appropriate to use. This includes how to take the product and when to see their doctor, if needed. The labeling on all OTC NSAIDs clearly states to stop use and ask a doctor if any new symptoms appear, or if pain gets worse or lasts more than 10 days, or if fever persists beyond 3 days. This information is on the label because continued pain or fever could be a sign of a more serious condition that requires physician intervention, not because the OTC medicines are unsafe. Additionally, OTC NSAIDs are not intended to be used for long durations unless directed by a physician and this is very clearly stated on the label.

It is important to remember that OTC NSAID medicines are safe for consumer use when used according to the label directions. These medicines have been extensively reviewed by FDA for their safety, and naproxen was switched in 1994 from prescription-to-OTC status based on extensive safety and efficacy data. These data were thoroughly reviewed against the proposed OTC indications by both FDA and the two advisory committees. In fact, approval of every OTC NSAID was based on FDA and advisory committee or panel review, and this process has confirmed that OTC NSAIDs are effective, have a wide margin of safety, and that the benefits of OTC NSAID use outweigh the risks.

In closing, because some of the drugs being discussed today may contain the same active ingredient as in some OTC analgesic medicines, it is important to clearly distinguish the benefit-to-risk equation for the prescription use of NSAIDs from that of OTC NSAIDs, which are taken at lower doses, for shorter durations, and for different uses. The millions of consumers who rely on OTC analgesics for temporary pain relief should continue to feel confident that these medicines are safe and effective when used according to the label.

DB-02/15/05