

Food and Drug Administration
Center for Drug Evaluation and Research

Arthritis Advisory Committee
Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

Discussion Issues
July 29, 2002
Pain (chronic)

1. A revised analgesic guidance may include indications intended to inform labels for the management of acute versus chronic pain, rather than a general pain claim. Please comment on the clinical relevance of this distinction in terms of efficacy and safety.
2. For both acute and chronic pain indications, arguments have been made for subcategories based on a mechanistic approach (i.e. nociceptive, neuropathic, hyperalgesic) and a clinical (i.e. cancer, musculoskeletal) approach. Please comment on the value of such approaches.
3. A chronic pain indication may require demonstration of efficacy in multiple models (examples may include: lower back pain, osteoarthritis, cancer pain, fibromyalgia and diabetic neuropathy). Please suggest other potential chronic pain models and discuss which chronic models may be most informative for labeling.
4. To support the generalizability of a chronic pain indication the division is considering replication in each of several models of chronic pain. The design of such studies may include:
 - a. studies in general of twelve weeks duration
 - b. superiority to either placebo or active control trial: background material to be provided
 - c. Primary endpoints including pain, function (as a patient reported outcome) and patient global assessments of therapyPlease comment on this proposed evidentiary base for an indication of chronic pain.
5. Please comment on the value of chronic lower back pain as a separate labeled indication vs. as part of a broader chronic pain claim (i.e. general or musculoskeletal). A revised analgesic guidance may include indications intended to inform labels for the management of acute versus chronic pain, rather than a general pain claim. Please comment on the clinical relevance of this distinction in terms of efficacy and safety.