May 5, 2004

Dear Arthritis Advisory Committee Members and Consultants:

It is my pleasure to invite you to participate in the FDA advisory committee meeting on June 2 and 3, 2004. Discussions over these two days will be focused on potential clinical trial designs and endpoints for the treatment of acute and chronic gout.

On June 2, you will be discussing the appropriate design of trials to demonstrate both efficacy and safety of new therapies for treatment of hyperuricemia associated with chronic gout. The discussion will include a specific NDA application for this indication.

On June 3, we will be exploring clinical trial designs for the treatment of acute gout. As individuals with acute gout often experience significant pain, it will be important to discuss potential pain based endpoints, along with other efficacy and safety endpoints. The presentation of a potential new therapy for this indication will be used as an example to stimulate discussion.

We are looking forward to seeing you on June 2 and 3 at the Advisory Committee Meeting Conference Room, 5630 Fishers Lane, Rockville, MD. Thank you in advance for sharing your expertise on this important public health issue relating to the future of gout management.

Sincerely,

Brian E. Harvey, M.D., Ph.D.
Acting Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research