

Beaumont Hospitals®

Human Investigation Committee

Phillip J. Bendick, Ph.D.
Chairperson

June 12, 2008

Kenneth Peters, MD
Department of Urology
Beaumont Hospitals - Royal Oak
William Beaumont Hospital
Urology

RE: **HIC #:** 2007-135
Protocol Title: AP021: AN OPEN-LABEL STUDY OF CC-10004 FOR CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME

Sponsor: Celgene Corporation

Dear Dr. Peters,

This project was reviewed by the Human Investigation Committee at the 6/6/2008 meeting. The above project and following documents (if applicable) were granted **FULL APPROVAL** on June 6, 2008. An Approval Extension until June 5, 2009 is granted. A Progress Report must be reviewed at a schedule meeting of the HIC prior to this expiration date, or HIC approval will expire.

- Protocol dated 5/12/08
- Consent form dated 6/11/08
- Investigator's Brochure dated 2/12/07

Any amendment to the protocol, except one necessary to eliminate apparent immediate hazard to a human subject, must be reviewed and approved by the Human Investigation Committee prior to initiation.

All Unanticipated Problems must be reported. Please refer to the HIC Policy #200 "Unanticipated Problems and Adverse Event Reporting" for definitions, guidance and timelines. All instances of study article (medication or device) error, or enrollment of subjects' not meeting enrollment criteria must be reported. Any deviation from the protocol that affects the health or safety of a study subject must be reported to the HIC within seven days of site's knowledge of the event.

Under terms of approval of this project, you agree to promptly notify the Chairman of the Human Investigation Committee, in writing, of the commencement of any legal action involving the project.

Sincerely,



Phillip J. Bendick, Ph.D.
Human Investigation Committee
Chairperson
/vkj