DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WRITTEN REQUEST – AMENDMENT 2

NDA 20-579

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: David R. Brill, Ph.D.
Director, Drug Regulatory Affairs
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Dr. Brill:

Please refer to your correspondence dated September 29, 2006, requesting changes to FDA's January 10, 2006, Written Request for pediatric studies for tamsulosin hydrochloride.

We have reviewed your proposed changes and are amending the Study Designs section of the Written Request as shown below. Deletions are indicated by strikethrough, additions are underlined. All other terms stated in our Written Request issued on January 10, 2006, and as amended on March 20, 2006, remain the same.

Study designs:

Study 1: An open-label study divided into a PK/PD characterization portion, followed by a long-term safety and tolerability portion. The PK/PD portion should include approximately 27 patients who are randomized to low, medium and high doses. This randomization should be stratified by weight (12.1 - 25 kg, 25.1 - 50 kg, and 50.1 - 100 kg). Day 1 pharmacokinetics should be characterized at the low dose in at least 9 ~~all~~ patients who are reasonably distributed across the three body weight ranges. ~~and t~~ Tamsulosin steady-state pharmacokinetics should be assessed in all patients when they finish 2 weeks of treatment on their final randomized dose level (i.e. on Day 14, 21 and 28 for the low, medium and high dose groups, respectively). When the PK portion of the trial is completed, the PK/PD and safety information should be shared with the Agency for our review. In addition, a comparison of the target pediatric exposure data against existing adult data should be provided in this report. Except for the first 27 patients who may continue in the study, no additional patients will be treated until the Agency has formally agreed that it is acceptable to do so. The sponsor must receive a formal statement from the Agency that patients who did not participate in the PK/PD portion of the study may begin treatment, increasing doses according to the individual's efficacious dose level.

Reports of the studies that meet the terms of the Written Request dated January 10, 2006, as amended on March 20, 2006, and by this letter, must be submitted to the Agency on or before July 1, 2009, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY"** in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger, to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Martin Kaufman, D.P.M., M.B.A., Regulatory Health Project Manager, at (301) 796-0928.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Julie Beitz

10/18/2006 01:59:08 PM