DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WRITTEN REQUEST – AMENDMENT 1

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 February 24, 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 Populations section of the Written Request as shown below. Deleted words are indicated by strikethrough. All other terms in our Written Request issued on January 10, 2006, remain the same.

Study populations, including sample sizes:

Study 1: For the PK/PD characterization, randomize approximately 27 patients, so that there are approximately 9 patients with PK/PD information for each dose level (low, medium and high) and for each body weight category (i.e. 12.1- 25 kg, 25.1-50 kg, and 50.1-100 kg). ~~Enroll sufficient numbers of patients across all age ranges.~~

For the long-term safety characterization, enroll a sufficient number of pediatric patients 2 years – 16 years of age with elevated detrusor LPP associated with a known neurological disorder (e.g. spina bifida) to ensure that approximately 75 and 50 patients receive tamsulosin hydrochloride for at least 6 months and 1 year, respectively.

Study 2: Enroll a sufficient number of patients to ensure that approximately 120 pediatric patients 2 years – 16 years of age with elevated detrusor LPP associated with a known neurological disorder (e.g. spina bifida) complete the study, with approximately 30 patients in each dose group (low, medium and high). Enroll sufficient numbers of patients of each age category (2-<5 years, 5-<10 years, and 10-16 years) ~~and body weight categories (12.1 - 25 kg, 25.1 - 50 kg, and 50.1 - 100 kg)~~ to allow for evaluation of consistency of effects.

Reports of the studies that meet the terms of the Written Request dated January 10, 2006, as amended 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

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