



**WRITTEN REQUEST – AMENDMENT 4**

NDA 21-493

Allergan, Inc.  
Attention: Ms. Elizabeth Bancroft  
Senior Director, Regulatory Affairs  
2525 Dupont Drive  
P.O. Box 19534  
Irvine, California 92623-9534

Dear Ms. Bancroft:

Please refer to your request to change to FDA's October 4, 2001, Written Request for pediatric studies for gatifloxacin.

We have reviewed your proposed changes and are amending the below-listed sections of the Written Request. All other terms stated in our Written Request issued on October 4, 2001, and as amended on July 2, 2002, and May 7, 2004, remain the same.

**Timeframe:**

The report of the above study must be submitted to the Agency on or before December 1, 2009. Please keep in mind that pediatric exclusivity only extends existing patent protection or exclusivity that has not expired or been previously extended at the time you submit your report of the study in response to this Written Request.

Reports of the studies that meet the terms of the Written Request dated October 4, 2001, as amended by this letter, must be submitted to the Agency on or before December 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 supplement to the 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 Lori M. Gorski, Project Manager, at (301) 796-0722.

Sincerely,

*{See appended electronic signature page}*

Edward M. Cox, M.D.  
Director  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Edward Cox  
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