HFD-104
D. MURPHY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-921

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

OCT 22 1999

Dear Ms. Bancroft:

Reference is made to your Proposed Pediatric Study Request submitted on August 6, 1999, for Ocuflox (ofloxacin ophthalmic solution) 0.3% to NDA 19-921.

To obtain needed pediatric information on ofloxacin for the treatment of bacterial conjunctivitis, the Food and Drug Administration (FDA) is hereby making a formal Written Request, pursuant to Section 505A of the Federal Food, Drug, and Cosmetic Act, that you submit information from the following study:

Type of Study:
The study should be a randomized, double-masked, parallel comparison trial. The study should be of at least 1 week duration and should include a minimum of three evaluations, for example, baseline, day 3±1 day, and end of treatment.

Indication/Objective:
The primary objective of the study should be to evaluate the safety and the clinical improvement rate between treatment groups. Enrolled patients should include male and female pediatric patients with a clinical diagnosis of bacterial conjunctivitis and a bacteria positive conjunctival culture.

Study Endpoints:
The primary endpoint should be clearing of the infection based on an external ophthalmologic examination. Additionally, conjunctival cultures must be taken between 2 and 10 days after the start of treatment.

Age Groups:
At least 100 culture positive patients between the ages of 0 and 1 month should be enrolled in the trial.

Drug Information:
Ofloxacin ophthalmic solution, 0.3% should be compared to a concurrent control.

Labeling:
Appropriate sections of the label may be changed to incorporate the findings of the study.

Format of Reports To Be Submitted:
A full study report not previously submitted to the Agency addressing the issues outlined in this request with full analysis, assessment, and interpretation.

Timeframe:
The report of the above study must be submitted to the Agency on or before October 1, 2002. 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 reports of the studies in response to this Written Request.

Please submit the protocol for the above study 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. Please notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. 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.

The report of this study should be submitted as a supplement to your approved NDA, with the proposed labeling changes you believe would be warranted based on the data derived from this study. When submitting the report, please 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. Please also send a copy of the cover letter of your submission, via fax (301-594-0183) or mail/messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, Maryland 20855-2773.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your applications. Submissions of proposed changes to this request should be clearly marked **"PROPOSED CHANGES IN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

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, please contact Joanne Holmes, M.B.A., Clinical Reviewer, at (301) 827-2090.

Sincerely,

Robert J DeLap 22 october 1999

Robert DeLap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
IND (b) (4)
NDA 19-921
HFD-550 Div Files
HFD-550/Proj Mgr/Gorski 10/1/99
HFD-550/DepDir/Chambers 10/1/99
HFD-550/MO/Boyd 9/30/99
HFD-550/SCSO/Zeccola
HFD-550/ClinRev/Holmes 9/22/99
HFD-105/ADRA/Walling
HFD-600/Office of Generic Drugs
HF-2/Lumpkin
HFD-002/T.Crescenzi
HFD-104/DMurphy

Drafted by: jh/September 22, 1999
Revised:
Filename: n19921pedrequest.doc

PEDIATRIC WRITTEN REQUEST LETTER
INFORMATION REQUEST (IR)