HFD-104/D. Murphy
Rec'd 5/24/00
Amendment

NDA 20-408

Merck Research Laboratories
Attention: Dennis M. Erb, Ph.D.
Senior Director, Regulatory Affairs
P.O. Box 4, BLA-20
Sumneytown Pike
West Point, Pennsylvania 19486

MAY 10 2000

Dear Dr. Erb:

Reference is made to your correspondence dated February 18, 2000, requesting changes to FDA's June 24, 1999, Written Request for pediatric studies for Trusopt (dorzolamide hydrochloride ophthalmic solution) Sterile Ophthalmic Solution, 2%. We also refer to our letter dated November 28, 1999.

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 June 24, 1999, remain the same.

Age Groups:
A minimum of 50 patients less than 2 years of age and a minimum of 50 patients from 2 through 5 years of age inclusive should be enrolled to receive dorzolamide hydrochloride monotherapy.

Drug Information:
Dorzolamide hydrochloride ophthalmic solution, 2% should be compared to timolol maleate ophthalmic gel forming solution.

The report of the study that meets the terms of the Written Request dated June 24, 1999, as amended by this letter, must be submitted to the Agency on or before March 31, 2003, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

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. 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.

The report of the 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 REPORT – 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 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, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked "PROPOSED CHANGES IN WRITTEN 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 Raphael Rodriguez, Regulatory Project Manager, at (301) 827-2090.

Sincerely yours,

Robert J DeLap 5/19/00

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

cc:
NDA 20-408
IND 32,761
HFD-550/Division file
HFD-550/PM/Rodriguez MR 5/3/00
HFD-550/SCSO/Vaccari
HFD-550/Dep Dir/Chambers WMC 5/1/00
HFD-550/MO/Lim
HFD-550/MO/Ludwig 05/10/00
HFD-550/Clin Rev/Holmes 5/3/00
HFD-105/Office Director/DeLap
HFD-600/Office of Generic Drugs
HFD-2/M.Lumpkin
HFD-104/D.Murphy
HFD-002/T.Crescenzi
HFD-550/Midthun 5/4/00
Drafted by: jh/April 14, 2000
Initialed by: Vaccari 5-3-00
Final:
filename: 20408WR2.doc

REVISED PEDIATRIC WRITTEN REQUEST LETTER
INFORMATION REQUEST (IR)