DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-408

Merck & Co., Inc.
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Reference is made to your correspondence dated December 21, 2001, requesting changes to FDA's June 24, 1999, Written Request for pediatric studies for dorzolamide.

We have reviewed your proposed changes and are amending the below listed section of the Written Request. All other terms stated in our Written Request issued on June 24, 1999, as amended May 19, 2000 remain the same.

Timeframe
The report of the study that meets the terms of the Written Request dated June 24, 1999, as amended May 19, 2000 and by this letter must be submitted to the Agency on or before June 30, 2004, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

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 these studies. When submitting the reports, 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 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, bold 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, contact Raphael Rodriguez, Regulatory Project Manager, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

Jonca C. Bull, M.D.
Acting Director
Office of Drug Evaluation V
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/

Jonca Bull

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