DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

WRITTEN REQUEST – AMENDMENT #1

IND 69,928

Merck & Co., Inc.
Attention: Robert A. Fromtling, Ph.D.
Director, Worldwide Regulatory Affairs
126 E. Lincoln Avenue
P.O. Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Dr. Fromtling:

Please refer to your correspondence dated February 5, 2007, requesting changes to FDA's August 18, 2006 Written Request for pediatric studies for MK-0518 (formerly L-000900612).

We reviewed your proposed changes and as agreed during the teleconference meeting between representatives of your firm and this Division on March 12, 2007, are amending the below-listed section of the Written Request. All other terms stated in our Written Request issued on August 18, 2006, remain the same.

Now reads: **Study Endpoints:**

Pharmacokinetics

Parameters including: C_{max}, C_{min}, $T_{max,}$ and AUC_{0-12}, will be characterized.

Instead of: **Study Endpoints:**

Pharmacokinetics

Parameters including: C_{max}, C_{min}, $T_{max,}$ $t_{1/2}$, AUC, and apparent oral clearance.

Reports of the studies that meet the terms of the Written Request dated August 18, 2006, as amended by this letter, must be submitted to the Agency on or before **June 30, 2011**, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Please 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.

Please submit reports of the studies as a supplement to an approved new drug application (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, please call Monica Zeballos, Pharm.D., Senior Regulatory Project Manager, at (301) 796-0840.

Sincerely yours,

{See appended electronic signature page}

Edward M. Cox, M.D.
Director
Office of Antimicrobial Products
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/

Edward Cox

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