DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-828
IND 41,099

Hoffman-La Roche, Inc.
Program Director, Drug Regulatory Affairs
Attention: Barbara S. Taylor, Ph.D.
340 Kingsland Street
Nutley NJ 07110-1199

Dear Dr. Taylor:

Reference is made to your correspondence dated October 29, 2001, requesting changes to FDA's April 9, 1999, Written Request for pediatric studies for saquinavir.

We have reviewed your proposed changes and are amending the section of the Written Request listed below. All other terms stated in our Written Request issued on April 9, 1999, remain the same.

**Timeframe for submitting reports of these studies**
Reports for the requested studies must be submitted to the Agency on our before **December 31, 2004** in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act. Please remember that pediatric exclusivity extends only existing patent protection or exclusivity that has not expired or been previously extended at the time you submit your reports of studies in response to this Written Request.

Please submit protocols for the above studies to your investigational new drug application (IND) 41,099 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.

Reports of the studies should be submitted as a supplement to your approved NDA 20-828 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. Also, please send a copy of the cover letter of your submission, via facsimile (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, contact Marsha Holloman, Regulatory Health Project Manager, at 301-827-2335.

Sincerely,

*{See appended electronic signature page}*

Mark Goldberger, MD, MPH
Director (Acting)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Mark Goldberger

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