DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

OUR STN: BL 103964/5065

MAY 13 2005

Hoffmann-La Roche, Inc.
Attention: Alan Mart
Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Mart:

Your request to supplement your biologics license application for Peginterferon alfa-2a to revise the "Clinical Pharmacology, Special Populations" section of the package insert to include pediatric pharmacokinetic information has been approved.

This fulfills your commitment number 4 of the October 16, 2002, approval letter for BL 103964/0, to submit data from ongoing study, NR16141 entitled "The Safety, Viral Kinetics and Pharmacokinetics of Pegasys® After Multiple Doses in Young Children with Chronic Hepatitis C Infection," to evaluate the safety and pharmacokinetics of Peginterferon alfa-2a in pediatric patients 2 to 8 years of age.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder biologics/default.htm for important information regarding therapeutic biological products, including the address for submissions Effective Oct 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

This information will be included in your biologics license application file.

Sincerely,

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

Enclosure: Package Insert