DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

OUR STN: BL 103964/5057

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 Warnings and Adverse Reactions sections of the package insert to include thrombotic thrombocytopenic purpura has been approved.

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

Enclosure: Package Insert