



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103145/5060

Hoffmann-La Roche, Inc.
Attention: Margaret Jack
Program Director
340 Kingsland Street
Nutley, NJ 07110

AUG 29 2006

Dear Ms. Jack:

Your request to supplement your biologics license application for Interferon alfa-2a to revise the package insert by including Infections and Pancreatitis subsections to the WARNINGS section and by including the terms hypertriglyceridemia/hyperlipidemia to the ADVERSE REACTIONS, Postmarketing subsection has been approved.

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).

Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Sincerely,

Debra Birnkrant
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research