DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103749/5006

JUL 29 2002

Encarnacion Suarez, Pharm.D.
Hoffmann-La Roche, Incorporated
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Suarez:

Your request to supplement your biologics license application for Daclizumab to include pediatric use and update the Clinical Pharmacology, Clinical Studies, and Adverse Reactions sections of the package insert with three year posttransplant data has been approved.

We acknowledge that you have fulfilled item numbers 2 and 3 of the post-licensure commitments detailed in the December 10, 1997 approval letter (Reference No. 97-0736 replaced with BL 103749/0).

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).

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

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Enclosure: Final draft labeling