DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-758/S-010 **CBE SUPPLEMENT**

Roche Palo Alto LLC
c/o Hoffmann-La Roche, Inc.
Attention: Mr. Anthony J. Corrado
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Corrado:

Please refer to your supplemental new drug application dated October 21, 2004, received October 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CellCept® Intravenous (mycophenolate mofetil hydrochloride for injection), 500 mg/vial.

This "Changes Being Effected" (CBE) supplement provides for the addition of the following sentences to the package insert (addition is double underlined), under the **DOSAGE AND ADMINISTRATION/Preparation of Infusion Solution (6mg/mL)** subsection,

> Caution should be exercised in the handling and preparation of solutions of CellCept Intravenous. Avoid direct contact of the prepared solution of CellCept Intravenous with skin or mucous membranes. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water. (See WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, and HANDLING AND DISPOSAL.)
>
> CellCept Intravenous does not contain an antibacterial preservative; therefore, reconstitution and dilution of the product must be performed under aseptic conditions. Additionally, this product is sealed under vacuum and should retain a vacuum throughout its shelf life. If a lack of vacuum in the vial is noted while adding diluent, the vial should not be used.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 21, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Christine Lincoln, R.N., MS, MBA, Labeling Reviewer at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

/s/

Renata Albrecht

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