CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-722/S-009

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-722/S-009 **CBE-30 SUPPLEMENT**

Hoffmann-La Roche Inc.
Attention: Christine Hoogmoed
Associate, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. Hoogmoed:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: CellCept® (mycophenolate mofetil) Capsules, 250 mg

NDA Number: 50-722

Supplement number: S-009

Date of supplement: May 11, 2001

Date of receipt: May 14, 2001

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 Days" proposes the following changes:

> The addition of a new bulk market drum for distribution within the United States to large-volume pharmacies to facilitate their repackaging operations, and the addition of an alternate contract packaging site [redacted] that may be used to package and label the product in the bulk market drum.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 13, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 14, 2001.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Attention: Document Room
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any question, call Matthew A. Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products
Office of 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/

Ellen Frank
5/21/01 12:19:53 PM
NDA 50-722/S-009