DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-722/S-007
NDA 50-723/S-004
NDA 50-759/S-005

Syntex (U.S.A.) LLC
Attention: Carmen Rodriguez, M.Sc.
Regulatory Program Director
3401 Hillview Avenue
Palo Alto, CA 94304

Dear Ms. Rodriguez:

Please refer to your supplemental new drug application dated February 18, 2000, received on February 22, 2000, for CellCept® (mycophenolate mofetil) Capsules, 250 mg (NDA 50-722/S-007). Refer also to your supplemental new drug applications dated May 19, 2000, received on May 24, 2000, for CellCept® (mycophenolate mofetil) Tablets, 500 mg (NDA 50-723/S-004), and CellCept® (mycophenolate mofetil) Oral Solution, 200 mg/mL (NDA 50-759/S-005). These supplements were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 20, 2000; June 16, 2000; November 30, 2000; December 6, 2000; December 12, 2000; December 14, 2000; and December 19, 2000.

These supplemental new drug applications provide for the use of CellCept® (mycophenolate mofetil) Capsules, Tablets, and Oral Solution for the prevention of acute rejection in pediatric renal transplant patients.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert submitted December 19, 2000.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For

administrative purposes, these submissions should be designated "FPL for approved supplemental NDAs 50-722/S-007, 50-723/S-004, 50-759/S-005." Approval of these submissions by FDA is not required before the labeling is used.

We note that your supplemental applications contain study reports and new labeling in response to your postmarketing commitment to further evaluate pediatric patients undergoing renal transplantation as reflected in the CellCept® Capsules approval letter of May 3, 1995:

> Continue current studies in pediatric populations. In addition, studies which would further characterize the pharmacokinetics of mycophenolate mofetil and its metabolites after the administration of IV and oral formulations, as well as activity of MPA from these formulations, should be undertaken in the pediatric population.

We have reviewed your submissions and conclude that the above commitment to study CellCept® oral formulations in pediatric patients undergoing renal transplantation was fulfilled. Your ongoing commitment to evaluate the pharmacokinetics, metabolism, and activity of CellCept® Intravenous in the pediatric population is the subject of a separate letter to NDA 50-758.

In addition, please submit three copies of the introductory materials that you propose to use to promote these products for use in pediatric renal transplant patients. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research