FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC) IMMUNOSUPPRESSIVE DRUGS SUBCOMMITTEE MEETING

QUESTIONS FOR THE SUBCOMMITTEE

January 24, 2002 Gaithersburg Holiday Inn Two Montgomery Village Avenue Gaithersburg, MD 20879

1.)	Do the data presented support the effectiveness and safety of cyclosporine withdrawal and concentration controlled sirolimus 2 to 4 months after kidney transplantation, in patients treated initially with a regimen of sirolimus, cyclosporine and corticosteroids?
	a.) If the answer is yes, should this consideration be restricted to a particular subpopulation? Conversely, is there a particular subpopulation for which cyclosporine withdrawal should not be considered?
	b.) If the answer is no, what additional information would be needed to support such a maintenance regimen?
2.)	What additional Phase 4 studies would you recommend?
3.)	Do you have any comments or recommendations regarding study design and/or endpoints for controlled clinical trials intended to support the safety and efficacy of maintenance immunosuppressive regimens in renal transplantation?