

FOOD AND DRUG ADMINISTRATION  
Center for Drug Evaluation and Research  
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING  
SUBCOMMITTEE FOR IMMUNOSUPPRESSANTS

**TENTATIVE 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 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 additional 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?

Note: These are tentative questions that may change before or at the time of the meeting.