

**Draft Discussion Points for the November 16, 2005 meeting,
Cardiovascular and Renal Advisory Committee**

Certican® (everolimus) for the prophylaxis of organ rejection in cardiac transplantation.

1. Both FDA and Novartis agree that fixed-dose everolimus in combination with “full-dose” cyclosporine should not be used for the prophylaxis of organ rejection in cardiac transplantation. Do committee members agree with this conclusion?
2. Do committee members believe there is sufficient information available to conclude that the regimen as proposed by Novartis has been demonstrated to be safe and effective for use in heart transplantation? In particular is there a subset of patients where treatment with everolimus/cyclosporine may be associated with a more favorable benefit/risk ratio?
3. If additional data is required for approval, please comment on what further information would be needed, and the possible design of studies to obtain this data.