



DIVISION OF CARDIO-RENAL DRUG PRODUCTS

Secondary Review

NDA: 21-526 (Ranexa; ranolazine for angina)

Sponsor: CV Therapeutics

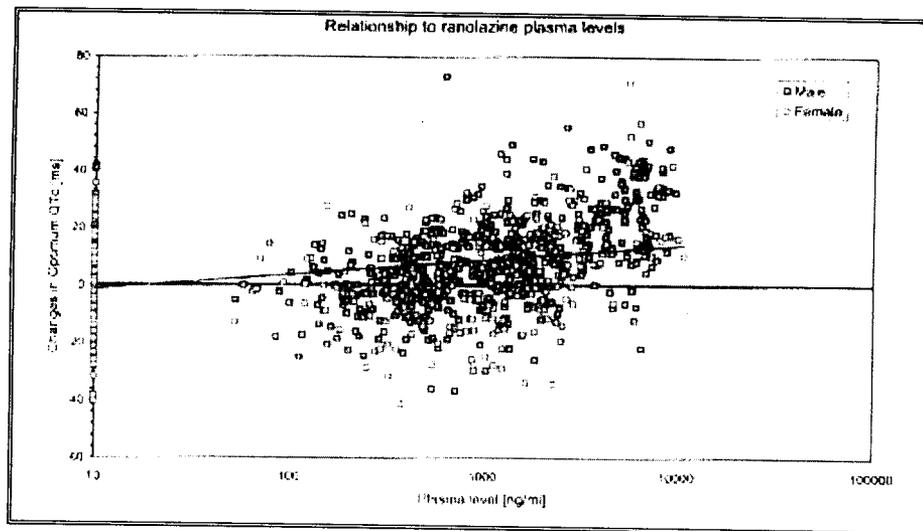
Review date: 7 November 2003

Reviewer: N. Stockbridge, M.D., Ph.D., HFD-110

Summary: This is an amendment to the secondary review of Ranexa, ranolazine for angina.

Distribution: NDA 21-526
HFD-110/Project Manager
HFD-860/Bhattaram/Gobburu

The original secondary review of ranolazine erroneously concludes that there is an escalating relationship between plasma level of ranolazine and QTc, based on this figure, taken from the sponsor's study report.



This figure is a plot of change in QTc vs. log of plasma level and the straight line is therefore a log-linear relationship, which is clearly inadequate to fit these data.

All of the available data from various studies are consistent with a linear relationship between plasma ranolazine levels and QTc.

