



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

STATISTICAL REVIEW AND EVALUATION (amendment of Clinical/Statistical Review of 12/04/02)

NDA #: 20-297

SERIAL #: SE8-009

DRUG NAME: Coreg (carvedilol)

INDICATION: to reduce mortality and the risk of infarction in clinically stable patients who have survived the acute phase of a myocardial infarction

SPONSOR: Glaxo SmithKline

DOCUMENT REVIEWED:

1. SAS data base in EDR

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STATISTICAL KEY WORDS: Change of primary endpoint, alpha allocation

Distribution: NDA 20-297, SE8-009

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The following table is to replace Table 10 of the clinical/statistical review dated 12/4/02, as a result of some minor changes because a few patients (six in the placebo group and one in the carvedilol group) were hospitalized and died on the same dates. These minor changes did not affect the reviewers' conclusions in the 12/4/02 review.

Table 10a. Time to event for death or cardiovascular hospitalization

Time (days)	CV hosp only		Death only		Death after hosp	
	Placebo N=216	Carvedilol N=224	Placebo N=78	Carvedilol N=65	Placebo N=73	Carvedilol N=51
Rand to hosp						
Mean	163	145	—	—	133	95
Median	98	81			68	51
Rand to death						
Mean	—	—	187	195	276	223
Median			148	93	233	185
Hosp to death						
Mean	—	—	—	—	142	128
Median					66	48