

## ERRATA TO FDA BRIEFING DOCUMENT

1. The following items in the briefing document need to be corrected. Deletions are indicated by strikethrough and corrections are in italics.
  - Page 7, last sentence, paragraph 3: ~~PBSA~~ replaced by *S. aureus bacteremia*.
  - Page 11, last sentence: It is noteworthy that only 44% of all study patients completed treatment with study medication and completed study participation to the TOC visit. ~~, thus limiting the number of patients in whom complete data were available.~~
  - Page 21, paragraph 2, third sentence, that reads, "Of these 32 patients, 10 died by TOC, including seven in the daptomycin group and three in the comparator group", and fourth sentence, that reads, "By post-study, there were two additional deaths in the daptomycin group and three in the comparator group", should be moved to end of the first paragraph. The patients discussed here refer to patients with microbiologic failures displayed in Table 15.
  - Page 21, paragraph 2, fourth sentence:

By post-study, there ~~were~~ *was two one* additional death in the daptomycin group and ~~three~~ *four* in the comparator group.
  - Page 22, title of Table 16: FDA Summary of ~~Failures All Patients in the Daptomycin Group~~ with Daptomycin MICs  $\geq 2$  mcg/ml
  - Page 36, first sentence:

Of the 9 ~~daptomycin~~ - *comparator* associated renal SAEs, three did not have a strong temporal relationship having occurred 21, 28, and 30 days after the final dose of the study drug.
  - Tables 23 and 24 need to be deleted and replaced by the following:

The following graph depicts the changes from baseline to peak of CPK measurements for all patients in the study. The point on the left of each line represents baseline CPK and the point on the right of each line represents the peak.

# Delta Graph for CPK Increases

LABTSTNM  
CK

ACTXDRNM [DEM]

