



MEMORANDUM

DATE: August 13, 2001

TO: Anti-Infective Drugs Advisory Committee Members and Guest Experts

FROM: Leo Chan, Regulatory Project Manager

SUBJECT: Comment on the 1992 Points To Consider Document on Clinical Development
And Labeling Of Anti-Infective Drug Products

The enclosed Points to Consider (PTC) document was initially published in 1992, and included advice on the selection of delta on pages 20-21. In February 2001, these two pages were revised, and the approach of basing delta on success rates was no longer used. Attached are both versions of pages 20-21 with the published date marked at the top of the page.

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