



MEMORANDUM

DATE: August 13, 2001

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

FROM: Daphne Lin, Statistical Team Leader, Division of Biometrics III

SUBJECT: Comments on the ICH E-10 Document

The entire ICH E-10 document will provide important background information to the choice of control group and related issues in clinical trials. With regard to the design of active control studies, please pay particular attention to the following sections:

1. Section 1.5 Assay Sensitivity page 7
2. Section 2.4 Active Control page 22

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