

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-789

STATISTICAL REVIEW(S)

MEMORANDUM

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

Date: August 26, 2003

To: LTJG Raquel Peat, M.S., M.P.H., USPHS
Regulatory Health Project Manager

From: Daphne Lin, Ph.D.
Statistical Team Leader, Division of Biometrics III

Subject: NDA 50-789, Tobramycin for Injection

This memorandum is in response to your consultation request on review of NDA 50-789 (Tobramycin for Injection). The American Pharmaceutical Partners submitted this NDA under the requirement of 505(b)(2).

I have reviewed this submission and discussed with the Medical Officer, Dr. Alma Davidson. Our conclusion is that there is no need to perform statistical analysis on this application.

Should any changes be requested in the future, statistical analysis will be performed on the information and the data available at that time.

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/s/

Raquel Peat
8/26/03 10:59:30 AM
CSO
Statistical Review
ready for sign off

Daphne Lin
8/26/03 11:07:54 AM
BIOMETRICS