

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-796

STATISTICAL REVIEW(S)

MEMORANDUM

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

Date: April 5, 2005

To: Chris Davi, M.S.
Regulatory Health Project Manager

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

Subject: NDA 50-796, Ceftriaxone for Injection and Dextrose Injection In the
DUPLEX Container

This memorandum is in response to your consultation request on review of NDA 50-796, Ceftriaxone for Injection and Dextrose Injection in the DUPLEX Container.

I have reviewed this submission and discussed with the review team members. 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.

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Daphne Lin
4/14/05 02:30:43 PM
BIOMETRICS