CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

60-666

APPROVAL LETTER

AF-13-675

May 7, 1970

Our Reference:
#60-666 - 146a.118

Dr. Colin West
Vice President, Production
Beecham Pharmaceuticals
65 Industrial South
Clifton, New Jersey 07012

Dear Dr. West:

The final printed package insert submitted on April 30, 1970, for TOTACILLIN (ampicillin trihydrate) FOR ORAL SOLUTION (125 mg./5 ml.) is acceptable. This completes the requirements for your Antibiotic Form 6 application of May 20, 1969, to manufacture this new drug product. You are now in a position to request certification of batches of this product when manufactured using the formulations submitted November 3, 1969, which do not contain _____. An approved copy of your Antibiotic Form 6 application is enclosed for your files.

The information contained in the Form 6 should be kept up to date. Whenever any changes are made in your manufacturing facilities or procedures, quality control procedures, packaging operations, labeling, etc., they should be reported to us promptly.

An expiration date of 12 months should be used on each batch of this product. A stability study should be set up on your first ___ certified batches of each potency and stability data submitted for inclusion in the Form 6 at six month intervals.

Sincerely yours,

Alan E. Smith, M.D., Director
Division of Anti-Infective Drugs
Office of New Drugs
Bureau of Drugs

cc:
NYK-DO
BD-240
BD-240/OD
BD-140 (Dr. Smith)
BD-430/Lab

JDHarrison:dc