000544

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

February 9, 1976

Our reference:
61-926

Biocraft Laboratories, Inc.
Attention: Harvey Richards
92 Route 46
Elmwood Park, New Jersey 07407

Gentlemen:

This is in reference to your Form 6 submission of April 10, 1975, which provides for the batch certification of amoxicillin trihydrate 250 mg. and 500 mg. capsules. The application as amended is now considered to be satisfactory. An approved copy is enclosed for your records.

Your firm is now in a position to request certification of batches of amoxicillin trihydrate 250 mg. and 500 mg. capsules, manufactured, controlled, packaged and labeled as described in the application. Batches of the drug under control numbers 5404, 5405, 5406, and 5407 were found to be satisfactory for certification.

The application as approved provides for a maximum batch size of 1,750,000 250 mg. capsules and 875,000 500 mg. capsules. An expiration date of eighteen months should be used on each batch of the drug submitted for certification. We have no objections to the stability testing program as provided for in the application. Stability data should be submitted as generated by the stability program.

The Form 6 application should be kept up-to-date. Any changes or revisions in the manufacturing process, controls, laboratory procedures or labeling should be submitted as an amendment to the Form 6 application.

Sincerely yours,

Marvin Seife

Marvin Seife, M.D., Director
Division of Generic Drug Monographs
Bureau of Drugs

Enclosure