DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

001693

Our reference: 62-703

JAN 15 1987

Harvey Richards
Assistant to the President
BIOCRAFT LABORATORIES, INC.
92 Route 46
Elmwood Park, New Jersey 07407

Dear Mr. Richards:

Reference is made to your Abbreviated Antibiotic Drug Application dated February 20, 1986, for Cephalexin for Oral Suspension USP, 125 mg/5 ml and 250 mg/5 ml.

We acknowledge receipt of your communications dated January 7, 1987, providing additional information.

We have completed our review of the application, and it is approved.

An expiration date of twenty-four (24) months should be used on each batch of the drug to be marketed and packaged as described in the application.

Place drug samples from the first three production batches into your stability program and test each batch at three (3) month intervals during the first year of aging, at six (6) month intervals during the second year, annually thereafter. As the data become available they should be furnished to this office at six (6) month intervals throughout the authorized shelf life of the subject drug.

For Initial Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final printed. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFN-240). Also, please do not use Form FD-2253 for this submission.

For Subsequent Campaigns: We call your attention to regulation 21 CFR 314.81(b)(3) which requires that all material for any subsequent advertising or promotional campaigns at the time of their initial use be submitted to our Division of Drug Advertising and Labeling (HFN-240) with a completed Form FD-2253. A copy of Form FD-2253 is enclosed for your convenience.

Please be reminded that since you are manufacturing the subject drug for the first time, that 21 CFR 314.81 requires that certain records and reports be submitted periodically.

The Abbreviated Antibiotic Drug Application should be kept up to date by submitting supplements whenever changes are contemplated in the manufacturing and/or laboratory procedures, controls, packaging, labeling, source of antibiotics, etc.

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drugs and Biologics

Enclosure