



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service **000973**

AADA 64-013

Food and Drug Administration
Rockville MD 20857

Bipcraft Laboratories, Inc.
Attention: Nora Buenviaje, Regulatory Associate
18-01 River Road
Fair Lawn, NJ 07410

Dear Madam:

This is in reference to your abbreviated antibiotic drug application dated August 14, 1991, submitted pursuant to Section 507 of the Food, Drug, and Cosmetic Act, for Amoxicillin Tablets USP, 250 mg (chewable).

We also acknowledge your communications dated July 24, August 28, and September 11, 1992 amending this abbreviated application.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your 250 mg chewable tablets to be bioequivalent to those of the listed drug (Beecham's AMOXIL® 250 mg chewable tablets). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "R. Williams", with a long horizontal flourish extending to the right.

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research



DECEMBER 22 1992