DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 40-133

NOV 30 1995

Royce Laboratories, Inc.
Attention: Loren Gelber, Ph.D.
16600 N.W. 54 Avenue
Miami, FL 33014

Dear Madam:

Reference is made to your abbreviated new drug application dated December 30, 1994, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act for Hydroxychloroquine Sulfate Tablets USP, 200 mg.

Reference is also made to your amendments dated September 11, October 11 and 30, 1995.

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 that your Hydroxychloroquine Sulfate Tablets USP, 200 mg, is bioequivalent and, therefore therapeutically equivalent, to the listed drug (Plaquenil® Tablets, 200 mg, of Sanofi Winthrop, Inc.). 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 FDA-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 FDA-2253 at the time of their initial use.

Sincerely yours,

Charles J. Ganley, M.D.

Charles J. Ganley, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research