DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 40-668

Food and Drug Administration
Rockville MD 20857

JUN 28 2006

Lyne Laboratories, Inc.
Attention: Robert E. Tarallo,
Vice President Research and Development
10 Burke Dr.
Brockton, MA 02301

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 8, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cyproheptadine Hydrochloride Syrup (Cyproheptadine Hydrochloride Oral Solution USP), 2 mg/5 mL.

Reference is also made to your amendments dated December 2, 2005; and March 7, March 31, May 31, and June 28, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Cyproheptadine Hydrochloride Syrup (Cyproheptadine Hydrochloride Oral Solution USP), 2 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Cyproheptadine Hydrochloride Syrup USP, 2 mg/5 mL, of Alpharma, U.S. Pharmaceuticals Division.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

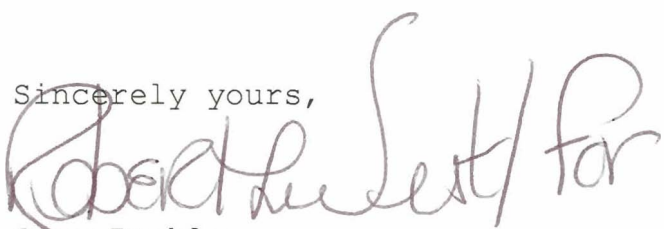
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research