ANDA 75-010

March 1, 1999

LNK International, Inc.
Attention: Pankaj S. Chudgar
60 Arkay Drive
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application dated November 27, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ibuprofen Tablets USP, 200 mg (round and capsule shaped tablets, colored brown).

Reference is also made to your amendments dated April 10, and August 1, 1997; March 5, August 10, August 14, and December 21, 1998; and January 4, January 19, and February 10, 1999.

We have completed the review of this abbreviated application and have concluded that the drug product is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined that your Ibuprofen Tablets 200 mg (round and capsule shaped tablets, colored brown) are bioequivalent to the listed drug product upon which the Agency relied as the basis of safety and effectiveness. 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 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research