ANDA 75-168

July 28, 1998

Par Pharmaceutical, Inc.
Attention: Michelle Bonomi-Huvala
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application dated July 17, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Naproxen Sodium Tablets USP, 220 mg (200 mg base), round and capsule-shaped.

Reference is also made to your amendments dated February 3, May 20, and July 20, 1998.

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 Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Naproxen Sodium Tablets USP, 220 mg (200 mg base) to be bioequivalent to the listed drug [Aleve**7** Tablets 220 mg (200 mg base) of Hamilton Pharmaceuticals Ltd.]. 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