ANDA 74-782

JUL 6 1998

Pharmaceutical Formulations, Inc.
Attention: Brian W. Barbee
460 Plainfield Avenue
Edison, NJ 08818

Dear Sir:

This is in reference to your abbreviated new drug application dated November 10, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ibuprofen Capsules 200 mg.

Reference is also made to your amendments dated September 8, December 15, and December 24, 1997; and January 23, April 15, May 18, May 29, June 8, and June 11, 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 drug product, Ibuprofen Capsules 200 mg, can be expected to have the same therapeutic effect as that of 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 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.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies which may be identified.

Sincerely yours,

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

7-6-88