ANDA 74-931

July 20, 1998

Novopharm N.C. Inc.
Attention: Therese M. Ast, Ph.D., Esq.
U.S. Agent for Novopharm Limited
4700 Novopharm Blvd.
Wilson, NC 27893

Dear Madam:

This is in reference to your abbreviated new drug application dated July 31, 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).

Reference is also made to your amendment dated June 18, and July 16, 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 Ibuprofen Tablets USP, 200 mg (round and capsule-shaped tablets) 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 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