CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75661

APPROVAL LETTER

ANDA 75-661

DEC 12 2001

BASF Corporation
Attention: Michael Gill
8800 Line Avenue
Shreveport, LA 71106

Dear Sir:

This is in reference to your abbreviated new drug application dated June 30, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ibuprofen Tablets USP, 200 mg (OTC).

Reference is also made to your amendments dated August 16, 1999; April 20, June 23, and October 31, 2000; and October 9, and November 13, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Ibuprofen Tablets USP, 200 mg to be bioequivalent to the listed drug (Nuprin® Tablets, 200 mg, of McNeil Consumer Products Company, Division of McNeilab Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, 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,

/S/ for

12/12/2001

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