ANDA 76-117 November 20, 2001

Reddy-Cheminor, Inc.
Attention: Paul V. Campanelli
U.S. Agent for: Dr. Reddy's Laboratories Limited
One Park Way
Upper Saddle River, NJ 07458

Dear Sir:

This is in reference to your abbreviated new drug application dated February 14, 2001, 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 May 11, August 16, and October 1, 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,

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