CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75588

APPROVAL LETTER

ANDA 75-588

APR 8 2002

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 (ANDA) dated February 19, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP, 200 mg and 30 mg, respectively, to be marketed as both round and capsule-shaped tablets.

Reference is also made to our Tentative Approval letter dated April 17, 2001, and to your amendments dated April 26, 1999; November 15, 2001; and January 25, and March 8, 2002.

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 round and capsule-shaped Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP, 200 mg and 30 mg, respectively, to be bioequivalent to the listed drug (Advil Cold and Sinus Tablets of Whitehall Laboratories, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, Advil Cold and Sinus Tablets of Whitehall Laboratories, Inc., is subject to a period of patent protection which expires on October 9, 2004 (U.S. Patent No. 4,552,899). Your application contains a patent certification to this patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use or sale of this drug product will not infringe on the patent and/or the patent is invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately

unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Pharmaceutical Formulations, Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Pharmaceutical Formulations, Inc. within the statutory forty-five day period. Furthermore, we note that the 180-day generic drug exclusivity previously granted to Ohm Laboratories, Inc. for this drug product expired on April 6, 2002.

Under Section 505A 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/

Gary Buehler 4/8/02
Director
Office of Generic Drugs
Center for Drug Evaluation and Research