ANDA 75-588 April 17, 2001

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 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.

Reference is also made to your amendments dated April 26, 1999; and January 17, January 22, March 2, March 8, and March 12, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug product is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing processes (CGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

The listed drug product 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.

However, we are unable to grant full approval to your application at this time because another abbreviated application for Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP, 200 mg/30 mg, containing a Paragraph IV Certification was accepted for filing by this office prior to receipt of your application. Accordingly, your application will be eligible for final approval beginning on the date that is one hundred and eighty days after the date the Agency receives notice of the first commercial marketing of the drug under the previous application, or the date of a court decision described under section 505(j)(5)(B)(iv), whichever is earlier. We refer you to the Agency=s guidance document A180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments@ (June 1998), for additional information.

To reactivate your application prior to final approval, please submit an amendment between 60 to 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. Please note that this amendment should be submitted even if none of these changes were made. The amendment should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current

good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to the date of final approval, you should amend your application accordingly.

At the time you submit any amendments, you should contact Ms. Elaine Hu, R.Ph., Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

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