MBennett

ANDA 74-916

JAN 9 1998

Alpharma
U.S. Pharmaceuticals Division
Attention: Vincent Andolina
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Sir:

Reference is made to your abbreviated new drug application dated June 25, 1996 submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ibuprofen Oral Suspension USP, 100 mg/5 mL, labeled for over-the-counter (OTC) use.

Reference is also made to your amendments dated September 24 and November 4, 1996; and April 15, April 22, May 2, August 15 and November 19, 1997.

The listed drug product referenced in your application is subject to a period of patent protection which expires on December 20, 2011 (patent 5,374,659, the '659 patent). Your application contains a Paragraph IV Certification to the '659 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(4)(B)(iii) of the Act provides that "approval shall be made effective immediately unless an action is brought for infringement of a 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 Alpharma has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Alpharma within the statutory forty-five day period. However, the listed drug product referenced in your application is also subject to a period of market exclusivity and therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(D) of the Act until the period has expired; i.e., June 16, 1998.

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

Please provide the Agency, at least 60 days prior to June 16, 1998, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an 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 this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application requires Agency approval before the changes may be made effective.

Prior to issuance of the final approval letter by the Agency, your 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, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to December 20, 2011, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mr. James Wilson, III, Project Manager, at (301) 827-5765 for further instructions.

The introduction or delivery for introduction into interstate commerce of the drugs before the effective approval date is prohibited under 21 U.S.C. 331 (d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research