

ANDA 75-217

December 16, 1998

L. Perrigo Company
Attention: Brian Schuster
117 Water Street
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application dated September 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ibuprofen Oral Suspension USP, 40 mg/mL (Concentrated Drops).

Reference is also made to your amendments dated January 9, January 28, June 9, October 26, and December 3, 1998.

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 patent certification 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 '659 patent. 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 L. Perrigo Company has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against L. Perrigo Company within the statutory forty-five day period. In addition, the listed drug product is also subject to a period of market exclusivity which expires on December 16, 1998.

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 Ibuprofen Oral Suspension, 40 mg/mL, to be bioequivalent to the listed drug (Children's Motrin® Concentrated Drops, 40 mg/mL, of McNeil Consumer Products Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require approved supplemental applications before the change may be made.

Post-marketing reporting requirements for these abbreviated applications 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,

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research