CENTER FOR DRUG EVALUATION AND RESEARCH

74-937

APPLICATION NUMBER:

APPROVAL LETTER

ANDA 74-937

DEC 22 1998

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

Dear Sir:

This is in reference to your abbreviated new drug application dated July 26, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ibuprofen Oral Suspension USP, 100 mg/5 mL.

Reference is also made to your amendments dated October 4, and November 13, 1996; and February 9, March 4, April 24, October 26, and December 17, 1998.

The listed drug referenced in your application is subject to a period of patent protection which expires on June 20, 2012 (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 was subject to a period of market exclusivity which expired on December 16, 1998.

Furthermore, the Act provides that approval of an abbreviated new drug application that contains a certification described in section 505(j)(2)(A)(vii)(IV) (a Paragraph IV Certification) and that provides for approval of the same drug product as that for which another abbreviated application containing a Paragraph IV

Certification was previously received, shall be made effective not earlier than one hundred and eighty (180) days after:

1. the date the Secretary receives notice from the applicant of the previous application that commercial marketing of the drug product approved in that application was initiated, or

2. the date of a decision of a court holding the patent which is the subject of the certification to be invalid or not infringed; whichever option occurs first [Section 505(j)(5)(B)(iv)].

The Office of Generic Drugs received and filed an application containing a Paragraph IV Certification to the '659 patent for Ibuprofen Oral Suspension, USP prior to receipt of your application. Accordingly, your application would not be eligible for full approval until 180-days following the earlier of event 1. or 2. noted above. We refer you to the Agency's guidance document entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments" (June 1998). However, in a communication dated December 17, 1998, the holder of the ANDA referred to above as being received and filed prior to your application has informed the Agency that it has relinquished its eligibility for the 180-day exclusivity with respect to Ibuprofen Oral Suspension USP, 100 mg/5 mL for OTC distribution. Thus, by relinquishing its eligibility for 180-day exclusivity, the prior applicant recognizes that the relinquishment will apply to all abbreviated new drug applications for this drug product (OTC labeling), and that the Office of Generic Drugs may approve any such application without regard to the 180-day exclusivity period specified in Section 505(j)(5)(B)(iv).

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, 100 mg/5 mL, to be bioequivalent to the listed drug (Children's Motrin®, 100 mg/5 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,

D. L. Spurn 12/22/98

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