DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-359

JAN 16 2004

L. Perrigo Company
Attention: Brian R. Schuster
515 Eastern Avenue
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 8, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ibuprofen Chewable Tablets, 50 mg Orange Flavored and 50 mg Grape Flavored; and 100 mg Orange Flavored and 100 mg Grape Flavored.

Reference is also made to your amendments dated November 20, 2002; January 14, and July 18, 2003; and January 9, 2004.

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 Chewable Tablets, 50 mg and 100 mg, to be bioequivalent to the listed drugs, Children's Motrin Chewable Tablets 50 mg, and Junior Strength Motrin® Chewable Tablets 100 mg, respectively, of McNeil Consumer Products Company. Your dissolution testing should be incorporated into the stability and quality contol program using the same method proposed in your application.

The listed drug products (RLD) referenced in your application, Children's Motrin Chewable Tablets 50 mg and Junior Strength Motrin Chewable Tablets 100 mg, of McNeil Consumer Products Company are subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 5,215,755 (the '755 patent) is scheduled to expire on December 1, 2010. Your application contains a paragraph IV patent certification to the '755 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '755 patent will not be infringed by your manufacture, use, or sale of

Ibuprofen Chewable Tablets, 50 mg and 100 mg. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against L. Perrigo Company (Perrigo) for infringement of the '755 patent which was the subject of the paragraph IV certification. This action must be brought against Perrigo prior to the expiration of forty-five days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Perrigo complied with the requirements of Section 505(j)(2)(B) of the Act, and that no legal action for infringement of the '755 patent was brought against Perrigo within the statutory forty-five day period.

With respect to 180-day generic drug exclusivity, we note that Perrigo was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '755 patent. Therefore, with this approval Perrigo is eligible for 180-days of market exclusivity for Ibuprofen Chewable Tablets 50 mg and 100 mg. This exclusivity will begin to run from the date Perrigo begins commercial marketing of the drug products.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The agency expects that you will begin commercial marketing of these drug products in a prompt manner. Please submit correspondence to your application stating the date you commenced commercial marketing of these products.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

Under Section 506A 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,

(b)(6)

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