ANDA 75-077 February 25, 2000

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 February 10, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Acetaminophen Extended-release Tablets, 650 mg.

Reference is also made to your amendments dated July 14, September 23, and December 20, 1999; and January 21, and January 24, 2000.

As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, 19th Edition, the "Orange Book", the listed drug product (RLD) referenced in your application, Tylenol Extended-release Tablets (currently marketed as Tylenol Arthritis Extended Relief Caplets) of McNeil Consumer Products Company, is subject to periods of patent protection. These periods expire on July 27, 2007 (U.S. Patents 5,004,613 and 4,820,522) and November 6, 2007 (U.S. Patent 4,968,509). Your application contains patent certifications under 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on any of the listed patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately unless an action for patent infringement is brought by either the patent holder or holder of the new drug application (NDA) for the RLD before the expiration of forty-five (45) days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the Agency that L. Perrigo Company (Perrigo) has complied with the requirements of Section 505 (j)(2)(B) of the Act and that no action for infringement of any of the listed patents was brought

against Perrigo within the statutory forty-five day period.

Furthermore, we have concluded that Perrigo was the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification to the three listed patents. Therefore, you are eligible for 180-days of market exclusivity for this drug product. Such exclusivity will begin to run either from the date Perrigo begins commercial marketing of this drug product, or from the date of a decision of a court finding the patent(s) invalid or not infringed, whichever occurs earlier (Section 505(j)(5)(B)(iv). A court decision that can trigger the beginning of exclusivity is a decision of any court in a patent infringement action resulting from a Paragraph IV Certification in which the court finds that the patent(s) is invalid or not infringed. 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 this drug product in a prompt manner. If you have a question concerning the Agency's determination of 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), or contact Mr. Donald Hare, Special Assistant to the Director, Office of Generic Drugs, at (301) 827-5845.

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 Acetaminophen Extended-release Tablets, 650 mg, to be bioequivalent to the listed drug (Tylenol Extended-release Tablets, 650 mg 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. The "interim" dissolution test and tolerances are:

The dissolution testing should be conducted in 900 mL of simulated gastric fluid w/o pepsin, pH 1.2, at 37^{0}C, using USP Apparatus II(paddles) at 50 rpm. The test product should meet the following "interim" specifications:

Time	% Dissolved
[	]
[	]
[	]
[	]

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. A "Special Supplement – Changes Being Effected" (zero) should be submitted if there are no revisions to be proposed to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances a Prior Approval supplement should be submitted.

Under 505 (j) 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,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research