DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-518

MAR 17 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 October 31, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-release Tablets, 200 mg (base)/120 mg.

Reference is also made to your amendments dated April 14, April 24, and May 15, 2003; and January 9, and March 12, 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 labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Naproxen Sodium and Pseudoephedrine Hydrochloride Extended-release Tablets, 200 mg (base)/120 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Aleve® Cold and Sinus Extended-release Tablets, 200 mg (base)/120 mg of Bayer Healthcare LLC).

Dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in [redacted] The test product should meet the following *interim* specifications:

Naproxen: Not less than [redacted] (Q) of the labeled amount of the drug in the dosage form is dissolved in 60 minutes.

Pseudoephedrine:

Time	Percent Dissolved
1 hour	(b)(4)
3 hour	
8 hour	

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. Data should be submitted as a "Special Supplement - Changes Being Effected" when there are no revisions to be made to the "interim" specifications, or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional

campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

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