ANDA 75-153 February 26, 1999

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 June 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Pseudoephedrine Hydrochloride Extended-release Tablets, 120 mg.

Reference is also made to your amendments dated September 23, 1997; July 7, September 18, November 4, November 9, and November 25, 1998; and January 26, February 11, February 22, and February 25, 1999.

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 Pseudoephedrine Hydrochloride Extended-release Tablets, 120 mg, to be bioequivalent to the listed drug (Sudafed® 12 Hour Extended-release Caplets, 120 mg, of Warner Wellcome Consumer Health Products). 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(s) and tolerances are:

Time	Dissolution
1 hour	
3 hours	
6 hours	

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. This supplemental application should be submitted under 21 CFR 314.70 (c)(1) when there are no revisions proposed for the "interim" specifications or when the final specifications are tighter than the interim specifications. In all other instances, the supplement should be submitted under 21 CFR 314.70(b)(2)(ii).

Under 21 CFR 314.70, 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,

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