ANDA 75-072 May 25, 1999

Duramed Pharmaceuticals, Inc.
Attention: John R. Rapoza, M.S., R.Ph.
5040 Lester Road
Cincinnati, OH 45213

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, for Verapamil Hydrochloride Extended-release Tablets USP, 120 mg and 240 mg.

Reference is also made to your amendments dated June 2, 13, December 10 and 17, 1997; June 19, and 25, 1998; and January 13, and April 12, 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 labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Verapamil Hydrochloride Extended-release Tablets USP, 120 mg and 240 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Isoptin® SR Sustained Release Oral Tablets, 120 mg and 240 mg of Knoll Pharmaceutical Co.).

Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 900 mL of simulated gastric fluid (SGF) without enzyme (first hour) and 900 mL of simulated intestinal fluid (SIF) without enzyme (second hour and thereafter) at 37^{0}C using USP 23 apparatus II (paddle) at 50 rpm. The test product should meet the following tentative specifications:

1 hr
2 hrs
3.5 hrs
5 hrs
8 hrs

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. The supplemental application should be submitted under 21 CFR 314.70 (c)(1) when there are no revisions to 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.

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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-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 FD-2253 at the time of their initial use.

Sincerely yours,

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