CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20943

APPROVAL LETTER

D. Ayeder

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-943

NOV 25 1998

Elan Pharmaceutical Research Corp.
Attention: Sharon L. Hamm, Pharm. D., R.Ph.
1300 Gould Drive
Gainesville, GA 30504

Dear Dr. Hamm:

Please refer to your new drug application (NDA) dated December 23, 1997, received December 29, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Verelan PM (verapamil hydrochloride) Capsules, 100, 200 and 300 mg.

We acknowledge receipt of your submissions dated February 3, 11, 12, 20, 24 and 26, March 3, 9, 19 and 20, May 12 (two) and 15, August 28 and 31, September 29, October 8, 13, 15, 16, 22 and 28 and November 9, 20 and 24, 1998.

This new drug application provides for the use of Verelan PM (verapamil hydrochloride) Capsules, 100, 200 and 300 mg for the management of essential hypertension.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted on November 25, 1998 and immediate container and carton labels submitted on November 23, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-943." Approval of this submission by FDA is not required before the labeling is used.

The approved dissolution specifications are as follows:

Time (hours)	% Dissolution
1	
4	
8	
11	
24	

Please note that since the *in vivo/in vitro* correlation was not properly validated, it cannot be used to support a waiver of bioequivalence studies for future manufacturing changes.

Please note also that approval of NDA 20-943 does not imply that changes can be made to your currently marketed product, Verelan Capsules, without notifying the Agency. Such changes should be submitted in supplements or annual reports to NDA 19-614 as appropriate.

In addition, the approved expiry date for the product is as follows:

100 mg: 18 months
200 and 300 mg: 24 months

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

/S/ 01/24/98

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research