

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20943

CORRESPONDENCE

JAN 6 1998

NDA 20-943

Elan Pharmaceutical Research Corporation
Attention: Roger Wayne Wiley, R.Ph.
1300 Gould Drive
Gainesville, GA 30504

Dear Mr. Wiley:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Verapamil PM (verapamil hydrochloride) Extended Release Capsules

Therapeutic Classification: S

Date of Application: December 23, 1997

Date of Receipt: December 29, 1997

Our Reference Number: NDA 20-943

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 27, 1998 in accordance with 21 CFR 314.101(a).

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

Natalla A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc

Original NDA

HFD-110

~~DISTRICT OFFICE~~

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ACKNOWLEDGMENT (AC)