DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-943/S-020

Elan Drug Delivery, Inc.
Attention: Roger Wayne Wiley, R.Ph.
Sr. Director, Regulatory Affairs
1300 Gould Drive
Gainesville, GA 30504

Dear Mr. Wiley:

Please refer to your supplemental new drug application dated October 31, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Verelan PM (verapamil hydrochloride) 100, 200, and 300 mg extended-release capsules.

This supplemental new drug application provides for a revised package insert with proposed new safety information about the co-administration of telithromycin and verapamil in the **PRECAUTIONS, Drug-Drug Interactions** subsection.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. Under the **PRECAUTIONS, Drug-Drug Interactions** subsection, your proposed text has been revised from:

   Hypotension, bradyarrhythmias, and lactic acidosis were observed in a patient receiving concurrent telithromycin, an antibiotic in the ketolide class of antibiotics.

   To:

   Hypotension, bradyarrhythmias, and lactic acidosis have been observed in patients receiving concurrent telithromycin, an antibiotic in the ketolide class of antibiotics.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the package insert submitted on November 1, 2006. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-943/S-020**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Denise M. Hinton, Regulatory Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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