NDA 20-648/S-002

Elan Pharmaceuticals, Inc. 11 APR 2001
Attention: Louise C. Johnson
Director, Regulatory Affairs
800 Gateway Boulevard
South San Francisco, CA 94080

Dear Ms. Johnson:

Please refer to your supplemental new drug application dated April 14, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diastat (diazepam rectal gel) Rectal Delivery System.

We acknowledge receipt of your amendment dated May 25, 1999.

Supplemental application S-002, submitted under "Changes Being Effected", provides for the modification of the commercially available container labels to consolidate the 10 mg adult and 10 mg pediatric container labels to a 10 mg universal container label. This change is also reflected in the package insert under the **HOW SUPPLIED** section.

We have completed the review of this supplemental application, S-002, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplement, have been made.

We additionally request, at the next printing, that you replace the presently used storage recommendations under the **HOW SUPPLIED** section with the following statement:

> "Store at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F) [see USP Controlled Room Temperature]"

This change may be reported in the next annual report.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research