DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-447

Elan Pharmaceuticals
Attention: Michael Scaife, PhD
7475 Lusk Boulevard
San Diego, CA 92121

Dear Dr. Scaife:

Please refer to your new drug application (NDA) dated October 31, 2001, received November 1, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for tizanidine 2 mg, 4 mg, and 6 mg capsules.

We acknowledge receipt of your submissions dated the following:

January 29, 2002
February 14, 2002
February 19, 2002
March 13, 2002
March 22, 2002
April 24, 2002
May 9, 2002
June 17, 2002
June 28, 2002
August 12, 2002
August 20, 2002
August 23, 2002
August 28, 2002 (2)
August 29, 2002 (2)

This new drug application provides for the use of tizanidine capsules for acute treatment of spasticity.

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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

You have agreed to the following dissolution method and specifications for all three capsule strengths:

Procedure:	As per (USP 23) <711>
Apparatus type:	USP Type II Apparatus (Rotating Paddles)
Medium:	b(4)
Volume (mL):	b(4)
Temperature:	b(4)
Speed of rotation (r.p.m.):	b(4)
Sample time (hours):	b(4)
Acceptance Specification:	b(4)

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). These revisions are terms of the NDA approval. 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 the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). 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. 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 21-447." Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55). Based on the information submitted, we are deferring submission of pediatric studies for patients under 16 years old until December 31, 2005.

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-42
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, call Lana Chen, R.Ph., Regulatory Management Officer, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Russell Katz
8/29/02 05:22:44 PM