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RESEARCH**

APPLICATION NUMBER:

21-447

PHARMACOLOGY REVIEW

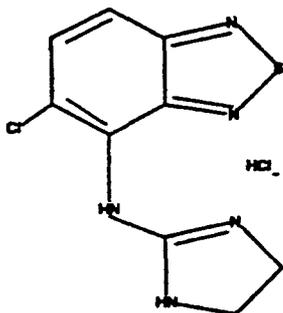
PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21-447
Review number: 21R
Sequence number/date/type of submission: Nov 5th 2001/Original NDA
Information to sponsor: Yes (x) No ()
Sponsor and/or agent: Elan Pharmaceuticals
San Diego, CA 92121

Reviewer name: Aisar Atrakchi, Ph.D.
Division name: Neuropharmacological Drug Products
HFD #: 120
Review completion date: Nov 20th 2001

Drug:

Trade name: Zanaflex
Generic name (list alphabetically): NA
Code name: tizanidine HCl
Drug Manufacturer: Elan Pharma,
Ireland
Chemical name: 5-chloro-4-(2-imidazolin-2-ylamino)-2,1,3-
benzothiazole hydrochloride
Molecular formula/molecular weight: C₉H₈CIN₅S-HCl/290.2
Structure:



Relevant INDs/NDAs/DMFs: N20-397

Drug class: centrally acting α_2 adrenergic receptor agonist
Indication: Spasticity
Clinical formulation: capsule
Route of administration: Oral

Executive Summary

I. Recommendations

A. Recommendation on Approvability: Not Applicable

B. Recommendation for Nonclinical Studies: standard nonclinical studies (pharmacology & toxicology), have been conducted and reviewed for tizanidine HCl tablets (N20-397) approved by the FDA in Nov 1996. Based on similar bioequivalence data for the approved tablet (2 & 4mg), and the proposed capsule (6mg) formulation, additional non-clinical studies are not required for the capsule form.

C. Recommendations on Labeling: same as used for the tablet form. When results from the _____ becomes available, the appropriate language will be incorporated into the label.

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/s/

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12/31/01 03:33:50 PM
PHARMACOLOGIST

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