CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

13-217 / S -041

Trade Name: **Skelaxin**

Generic Name: **metaxalone**

Sponsor: **Elan Pharmaceuticals**

Approval Date: **September 26, 2001**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

13-217 / S -041

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	X
Chemistry Review(s)	
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

13-217 / S -041

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-217/S-041

Elan Pharmaceuticals
Attention: Michael C. Scaife, Ph.D.
Vice President, Regulatory Affairs
45 Horse Hill Road
Ceder Knolls, NJ 07927

Dear Dr. Scaife:

Please refer to your supplemental new drug application dated March 23, 2001, received March 26, 2001 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin, (metaxolone) Tablets 400 mg.

We acknowledge receipt of your amendments dated September 20 and September 25, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for replacing b(4) nc to compact the drug substance.

We have completed the review of this supplemental application, and it is approved.

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 Sharon Schmidt, M.S., Project Manager, at (301) 827-2536.

Sincerely,

{See appended electronic signature page}

John Smith, Ph. D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products, (HFD-550)
DNDC III, Office of New Drug Chemistry
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/

John Smith
9/26/01 03:01:01 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

13-217 / S -041

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division HFD-550	2. NDA Number 13-217
3. Name and Address of Applicant Elan Pharmaceuticals 45 Horse Hill Road Ceder Knolls, NJ 07927	**4. Supplement Number:** SCM 041 **Letter Date:**3/23/2001 **Stamp Date:** 3/26/2001 **Due Date :** 9/26/2001	
5. Name of Drug Skelaxin ® Tablets	**6. Nonproprietary Name** Metaxalone Tablets	
7. Supplement Provides for: b(4) Replacing [redacted] the DS.		**8. Amendment(s)** SC Dated 9/20/01 (b)(4) Fax Dated 9/25/01
9. Pharmacological Category Skeletal Muscle Relaxant.	**10. How Dispensed** Rx	**11. Related Documents**
12. Dosage Form Tablets	**13. Potency(ies)** 400 mg	

14. Chemical Name and Structure

See USAN

15. Comments

This is a CBE 30 supplement with a SUPAC Level 3 change. The applicant did not fulfill all the requirements of a SUPAC-IR Level 3 change in the initial submission (for details see attached notes on pages 2-6 of this review). These requirements have been fulfilled subsequently in the fax of 9/20/2001 (for details see attached notes on pages 7-11 of this review).

16. Conclusions and Recommendations

It is recommended that the supplement be approved.

17. Name	Signature	Date
Vispi P. Bhavnagri, Ph.D., Review Chemist		
Concurrence John Smith, Ph.D. Chemistry Team Leader		

APPROVE

Doc ID: ZIP#1\Review\Suppl.\ 13217_41_Rev.doc

10 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1

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

/s/

Vispi Bhavnagri
9/26/01 02:28:29 PM
CHEMIST

John Smith
9/26/01 02:54:38 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

13-217 / S -041

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-217/S-041 **CBE-30/CBE-0 SUPPLEMENT**

Elan Pharmaceuticals, Inc.
Attention: Micheal C. Scaife, Ph.D.
Vice President, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, NJ 07927

Dear Dr. Scaife,

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

Name of Drug Product:	Skelaxin (metaxalone) Tablets 400mg
NDA Number:	13-217
Supplement number:	S-041
Date of supplement:	March 23, 2001
Date of receipt:	March 26, 2001

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," proposes the following change: Adding a [redacted] or the drug substance metaxalone at [redacted]

b(4)

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 May 22, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be 6-Month Goal Date.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesics and Ophthalmic Drug Products, HFD-550
Attention: Document Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesics and Ophthalmic Drug Products, HFD-550
Attention: Document Control Room
9201 Corporate Boulevard, HFD-550
Rockville, Maryland 20857

If you have any question, call Sharon Schmidt, Regulatory Project Manager, at (301) 827-2536.

Sincerely yours,

Sharon A. Schmidt
Acting Supervisory CSO
Division of Anti-Inflammatory, Analgesic
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/s/

Sharon Schmidt
3/27/01 04:13:25 PM