CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

13-217 / S -043

Trade Name: **Skelaxin**

Generic Name: **metaxalone**

Sponsor: **Elan Pharmaceuticals**

Approval Date: **April 16, 2002**

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APPLICATION NUMBER:

13-217 / S -043

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-217/S-043

Elan Pharmaceuticals
Attention: Linda Ballai Fischer
Director, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, NJ 07927

Dear Ms Fischer:

Please refer to your supplemental new drug application dated October 15, 2001, received October 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin (metaxalone) Tablets 400 mg.

We acknowledge receipt of your submission dated April 12, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for ——— ——— s an alternate packaging site for the 100 and 500 count bottles.

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 Jane Dean, Consumer Safety Officer/PM, at 301-827-2090.

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

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/s/

John Smith
4/16/02 02:31:50 PM

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APPLICATION NUMBER:

13-217 / S -043

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 043 **Letter Date:** 10/15/01 **Stamp Date:** 10/16/01 **Due Date :** 4/16/01	
5. Name of Drug Skelaxin ® Tablets	**6. Nonproprietary Name** Metaxalone Tablets	
7. Supplement Provides for: [redacted] nc. as an alternate packaging site for the 100 and 500 count bottles		**8. Amendment(s)** Fax dated 4/3/02
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. The packaging facility had a satisfactory cGMP inspection on 2/26-28/02. Other review notes are attached.		
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		

Zip #1\Review\Suppl.\13-217_043_Rev.Doc

APPROVAL

1 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1

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/s/

Vispi Bhavnagri
4/15/02 10:51:44 AM
CHEMIST

John Smith
4/16/02 11:22:21 AM
CHEMIST

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APPLICATION NUMBER:

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA13-217/S-043

CBE-30/CBE-0 SUPPLEMENT

Elan Pharmaceuticals
Attention: Linda Ballai Fischer
Director, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, NJ 07927

Dear Ms. Fischer:

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) Tablet, 400mg

NDA Number: 13-217

Supplement number: S-043

Date of supplement: October 15, 2001

Date of receipt: October 16, 2001

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," proposes the addition of a new drug product packager.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on December 15, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions, please contact Ms. Jane A. Dean, Regulatory Project Manager, at (301) 827-2090.

Sincerely yours,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research