CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

13-217 / S -040

Trade Name: **Skelaxin**

Generic Name: **metaxalone**

Sponsor: **Elan Pharmaceuticals**

Approval Date: **July 31, 2001**

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APPLICATION NUMBER:

13-217 / S -040

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APPLICATION NUMBER:

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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-40

Elan Pharmaceuticals, Incorporated
Attention: Richard Shupack
Senior Director, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, New Jersey 07927

Dear Mr. Shupack:

Please refer to your supplemental new drug application dated January 30, 2001, received January 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin (metaxalone) Tablets 400 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change of stability testing labs [redacted] b(4)

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
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
7/31/01 02:51:04 PM

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APPLICATION NUMBER:

13-217 / S -040

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, N>. J. 07927	**4. Supplement Number:** SCM 040 **Letter Date:** 1/30/01 **Stamp Date:** 1/31/01 **Due Date :** 7/31/01	
5. Name of Drug Skelaxin® Tablets	**6. Nonproprietary Name** Metaxalone	
7. Supplement Provides for: Post approval change of analytical testing labs [redacted] om the		**8. Amendment(s)** None b(4)
9. Pharmacological Category Skeletal Muscle Relaxant	**10. How Dispensed** Rx	**11. Related Documents** None
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 company has met all of the four following requirements for this supplement to qualify as a CBE 30 supplement for an analytical site change:

1. The applicant has indicated that the same test methods will be used (Certificate on page 7)

2. All post-approval commitments have been fulfilled (Certificate on page 7)

3. The new site is capable of performing the analysis (Certificate on page 7 and acceptable EER dated 2/20/01)

4. The new facility has a satisfactory cGMP inspection (Certificate on page 7)

16. Conclusions and Recommendations

The company has complied with all four requirements [redacted] . It is therefore recommended that the b(4) supplement be approved.

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

APPROVE

Doc. ID: Zip #1\Review\Suppl.\13-217_SCM040_rev.Doc

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/s/

Vispi Bhavnagri
7/26/01 01:42:37 PM
CHEMIST

John Smith
7/26/01 02:36:19 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

13-217 / S -040

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-217/S-040

CBE-30 SUPPLEMENT

Elan Pharmaceuticals
Attention: Michael Scaife
Vice President, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, New Jersey 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-040

Date of Supplement: January 30, 2001

Date of Receipt: January 31, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days"

b(4)

Unless we notify you within 60 days of our 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 on March ??, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be March 23, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application 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

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and

Ophthalmic Drug Products, HFD-550
Attention: Central Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Ophthalmic Drug Products, HFD-550
Attention: Central Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call me at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Sharon Schmidt, M.A.
Project Manager
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Sharon Schmidt
6/14/01 04:19:13 PM