

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

13-217 / S -045

***Trade Name:* Skelaxin**

***Generic Name:* metaxalone**

***Sponsor:* Elan Pharmaceuticals**

***Approval Date:* June 3, 2002**

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13-217 / S -045

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APPROVAL LETTER



NDA 13-217/S-045

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 November 11, 2001, received December 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelaxin® (400 mg metaxalone) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a revised analytical method for the drug substance (stability testing) and the drug product (release and stability testing), and a revised analytical method for the _____ the drug product. (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 Jane Dean, Consumer Safety Officer, at (301) 827-2040

Sincerely,

{See appended electronic signature page}

John Smith, Ph.D.
Chemistry Team Leader
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

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APPLICATION NUMBER:

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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 Cedar Knolls, NJ 07927 | 4. Supplement Number: SCS 045 Letter Date: 11/30/01 Stamp Date: 12/3/01 Due Date : 6/3/01 | |
| 5. Name of Drug Skelaxin [®] Tablets | 6. Nonproprietary Name Metaxalone Tablets | |
| 7. Supplement Provides for: Revision of two methods. One method is used to test the stability of the DS as well as the stability and release testing of the DP. The second method is for testing the _____ f the DP. | | 8. Amendment(s) b(4) |
| 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. Two methods are validated. The validations are satisfactory (See attached notes). | | |
| 16. Conclusions and Recommendations Recommend approval. | | |
| 17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist | Signature | Date |
| Concurrence John Smith, Ph.D. Chemistry Team Leader | | |

Zip #2\Review\Suppl.\13-217_045_Rev.Doc

APPROVAL

6 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

Withheld Track Number: Chemistry-1

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/s/

Vispi Bhavnagri
6/4/02 08:57:59 AM
CHEMIST

John Smith
6/4/02 09:13:39 AM
CHEMIST

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APPLICATION NUMBER:

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ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



NDA 13-217/S-045

CBE-30 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, 400mg)
NDA Number: 13-217
Supplement number: S-045
Date of supplement: November 30, 2001
Date of receipt: December 3, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes a change in the analytical procedure for metaxalone.

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 on January 31, 2002, 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, 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

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/s/

Lori Gorski

12/5/01 12:04:14 PM

Lori Gorski has signed for Carmen DeBellas