CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

13-217 / S -037

Trade Name: **Skelaxin**

Generic Name: **metaxalone**

Sponsor: **Elan Pharmaceuticals**

Approval Date: **May 4, 2000**

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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-037

Carnrick Laboratories
Division of Elan Pharmaceuticals
Attention: Delores M. Turnage
Manager, Regulatory Affairs
45 Horse Hill Road
Cedar Knolls, New Jersey 07927

MAY 4 2000

Dear Ms. Turnage:

Please refer to your supplemental new drug application dated November 11, 2000, received November 16, 2000, 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 _____ rather than a fixed time.

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,

Mona Zarifa

Mona Zarifa, Ph.D.
Acting 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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APPLICATION NUMBER:

13-217 / S -037

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division HFD-550	2. NDA Number 13-217 MAY 10 2000
3. Name and Address of Applicant Carnrick Laboratories Inc. 65 Horse Hill Road Ceder Knolls, NJ 07927	**4. Supplement Number:** SCS 037 **Letter Date:**11/11/99 **Stamp Date:** 11/16/99 **Due Date :** 5/14/00	
5. Name of Drug Skelaxin ® Tablets	**6. Nonproprietary Name** Metaxolone Tablets	
7. Supplement Provides for: b(4) ather than for a fixed time period (CBE 30)		**8. Amendment(s)** b(4)
9. Pharmacological Category Skeletal Muscle Relaxant.	**10. How Dispensed** Rx	**11. Related Documents** N 13-217/S33
12. Dosage Form Tablets	**13. Potency(ies)** 400 mg	

14. Chemical Name and Structure

See USAN

15. Comments

The change was approved in supplement 33, and implemented by the alternate contract manufacturer, but not by the primary manufacturer. This supplement was submitted to institute this change also by the primary contract manufacturer. For details see attached Review Notes.

16. Conclusions and Recommendations

The applicant has complied with all the requirements of a SUPAC Level-2 process change. It is recommended that the supplement be approved.

17. Name	Signature	Date
Vispi P. Bhavnagri, Ph.D., Review Chemist	Vispi P. Bhavnagri	5/10/00
Concurrence Mona Zarifa, Ph.D., Acting Chemistry Team Leader	Mona Zarifa	5/10/00

2 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1

cc:
NDA 13-217
HFD-550/Division File
HFD-550/V.Bhavnagri
HFD-550/S.Schmidt
HFD-550/M.Zarifa
HFD-830/Cw.Chen
APPROVE

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-217/S-037

Carnrick Laboratories
45 Horse Hill Road
Cedar Knolls, NJ 07927

DEC 29 1999

Attention: Dolores M. Turnage
Manager, Regulatory Affairs

Dear Ms. Turnage:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Skelaxin Tablets (metaxalone)

NDA Number: 13-217

Supplement Number: S-037

Date of Supplement: November 11, 1999

Date of Receipt: November 16, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on January 15, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Sharon A. Schmidt 12/29/99

Karen Midthun, M.D.
Acting Division Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 13-217/S-037
HFD-550/Div. Files
HFD-550/CSO/Schmidt, S

SUPPLEMENT ACKNOWLEDGEMENT