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
## APPLICATION NUMBER:

13-217 / S -037

## CONTENTS

<table>
<thead>
<tr>
<th>Reviews / Information Included in this NDA Review.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
</tr>
<tr>
<td>Approvable Letter</td>
</tr>
<tr>
<td>Labeling</td>
</tr>
<tr>
<td>Summary Review</td>
</tr>
<tr>
<td>Officer/Employee List</td>
</tr>
<tr>
<td>Office Director Memo</td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
</tr>
<tr>
<td>Medical Review(s)</td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
</tr>
<tr>
<td>Environmental Assessment</td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
</tr>
<tr>
<td>Statistical Review(s)</td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:

13-217 / S -037

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

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, 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
APPLICATION NUMBER:

13-217 / S -037

CHEMISTRY REVIEW(S)
<table>
<thead>
<tr>
<th>Chemistry Review #1</th>
<th>1. Division</th>
<th>2. NDA Number</th>
<th>MAY 10 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HFD-550</td>
<td>13-217</td>
<td></td>
</tr>
<tr>
<td>3. Name and Address of Applicant</td>
<td>4. Supplement Number: SCS 037</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnrick Laboratories Inc.</td>
<td>Letter Date: 11/11/99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 Horse Hill Road</td>
<td>Stamp Date: 11/16/99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ceder Knolls, NJ 07927</td>
<td>Due Date: 5/14/00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Name of Drug</td>
<td>6. Nonproprietary Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skelaxin® Tablets</td>
<td>Metaxolone Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Supplement Provides for:</td>
<td>b(4)</td>
<td>other than for a fixed time</td>
<td>b(4)</td>
</tr>
<tr>
<td>period (CBE 30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skeletal Muscle Relaxant.</td>
<td>Rx</td>
<td>N 13-217/S33</td>
<td></td>
</tr>
<tr>
<td>12. Dosage Form</td>
<td>13. Potency(ies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tablets</td>
<td>400 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>17. Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vispi P. Bhavnagri, Ph.D., Review Chemist</td>
<td>Vispi P. Bhavnagri</td>
<td>8/10/00</td>
</tr>
<tr>
<td>Concurrence</td>
<td>Mona Zarifa, Ph.D., Acting Chemistry Team Leader</td>
<td>5/10/00</td>
</tr>
</tbody>
</table>
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
APPLICATION NUMBER:

13-217 / S -037

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
NDA 13-217/S-037

Carnrick Laboratories
45 Horse Hill Road
Cedar Knolls, NJ 07927

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,

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