CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-835/S011

Trade Name: Actonel Tablets

Generic Name: risedronate sodium

Sponsor: Proctor and Gamble Pharmaceuticals, Inc

Approval Date: November 2, 2002
**APPLICATION NUMBER:**
NDA 20-835/S011

**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>Medical Review(s)</td>
</tr>
<tr>
<td>Chemistry Review(s)</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>Administrative/Correspondence Document(s)</td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:
NDA 20-835/S011

APPROVAL LETTER
NDA 20-835/S-011

Procter and Gamble Pharmaceuticals, Inc.
Attention: Lenore Faulhaber, Ph.D., M.B.A.
Manager, U.S. Regulatory Affairs
Health Care Research Center
8700 Mason-Montgomery Road, SB4-2K2
Mason, OH 45040-9462

Dear Dr. Faulhaber:

Please refer to your supplemental new drug application dated July 11, 2002, received
July 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for
Actonel (risedronate sodium) Tablets.

This supplemental new drug application provides for an alternate blister package that contains
for Actonel 35 mg Tablets.

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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301)
827-6392.

Sincerely,

{See appended electronic signature page}

Sheldon Markofsky, Ph.D.
Acting Chemistry Team Leader II, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
Office of New Drug Chemistry
Center for Drug Evaluation and Research
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sheldon Markofsky
11/5/02 11:00:18 AM
<table>
<thead>
<tr>
<th>CHEMIST'S REVIEW</th>
<th>1. ORGANIZATION</th>
<th>2. NDA NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DMEDP, HFD-510</td>
<td>20-835</td>
</tr>
<tr>
<td>3. NAME AND ADDRESS OF APPLICANT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procter &amp; Gamble Pharmaceuticals, Inc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8700 Mason Montgomery Road</td>
<td>SCP-011, 7/11/02</td>
<td></td>
</tr>
<tr>
<td>Mason, OH 45040-9462</td>
<td>User Fee date: (PA supplement)</td>
<td></td>
</tr>
<tr>
<td>5. NAME OF THE DRUG</td>
<td>6. NONPROPRIETARY NAME</td>
<td>11/12/02 (4 months)</td>
</tr>
<tr>
<td>Actonel® tablets</td>
<td>Risedronate sodium</td>
<td></td>
</tr>
<tr>
<td>7. SUPPLEMENT PROVIDES FOR:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An alternate blister package for Actonel 35 mg tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. PHARMACOLOGICAL CATEGORY</td>
<td>10. HOW DISPENSED</td>
<td>11. RELATED IND/ND/DA/DMF</td>
</tr>
<tr>
<td>Treatment and prevention of osteoporosis.</td>
<td>Rx</td>
<td></td>
</tr>
<tr>
<td>Treatment of Paget's disease of bone.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. DOSAGE FORM</td>
<td>13. POTENCY</td>
<td></td>
</tr>
<tr>
<td>Tablet</td>
<td>5 &amp; 30 and 35 mg</td>
<td></td>
</tr>
</tbody>
</table>

14. CHEMICAL NAME AND STRUCTURE.

![Chemical Structure]

1-Hydroxy-1-phosphono-2-pyridin-3-yl-ethyl-phosphonic acid, monosodium salt, C$_7$H$_{10}$NO$_7$P$_2$Na$_2$.5H$_2$O

15. COMMENTS

Supplement 011 has been submitted, in electronic format, to HFD-510 as a PA supplement. It provides for the use an alternate blister package that contains [as the blister packaging film].

16. CONCLUSION AND RECOMMENDATION

From a chemistry standpoint, the supplement can be approved.

17. NAME REVIEWER SIGNATURE DATE COMPLETED

Elsbeth G. Chikhale, Ph.D. 10/24/02

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Init. by:


HPD-510/ S Markofsky / R Hedin / EG Chikhale/Division file/NDA 20-835
6 Page(s) Withheld

√ § 552(b)(4) Trade Secret / Confidential

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Elisbeth Chikhaile
10/31/02 09:42:02 AM
CHEMIST

Sheldon Markofsky
10/31/02 02:07:23 PM
CHEMIST
NDA 20-835/S-011

PRIOR APPROVAL SUPPLEMENT

Procter & Gamble Pharmaceuticals, Inc.
Attention: Lenore Faulhaber, Ph.D., M.B.A.
Manager, U.S. Regulatory Affairs
Health Care Research Center
8700 Mason Montgomery Road, SB4-2K2
Mason, OH 45040-9462

Dear Dr. Faulhaber:

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: Actonel (risedronate sodium) Tablets

NDA Number: 20-835

Supplement Number: S-011

Date of Supplement: July 11, 2002

Date of Receipt: July 12, 2002

This supplement proposes an alternate blister package for Actonel 35 mg Tablets.

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 September 10, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 12, 2002.

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/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Fishers Document Room 8B-45
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6392.

Sincerely,

(See appended electronic signature page)

Randy Hedin, R.Ph.
Senior Regulatory Management Officer
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Randy Hedin
8/8/02 04:32:15 PM