CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-835/S012

Trade Name: Actonel Tablets

Generic Name: risedronate sodium

Sponsor: Proctor and Gamble Pharmaceuticals, Inc

Approval Date: December 10, 2002
**Center for Drug Evaluation and Research**

**APPLICATION NUMBER:**
NDA 20-835/S012

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APPLICATION NUMBER:
NDA 20-835/S012

APPROVAL LETTER
NDA 20-835/S-012

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 August 14, 2002, received August 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) Tablets.

We acknowledge receipt of your submission dated August 15, 2002.

This supplemental new drug application provides for an alternate manufacturing site for Actonel 5 mg Tablets at Procter & Gamble Pharmaceuticals Puerto Rico, Inc., Manati, Puerto Rico.

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
12/10/02 02:59:48 PM
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-835/S012

CHEMISTRY REVIEW(S)
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3. NAME AND ADDRESS OF APPLICANT
Procter & Gamble Pharmaceuticals, Inc.
Health Care Research Center
8700 Mason Montgomery Road
Mason, OH 45040-9462

4. SUPPLEMENT NUMBER, DATE
SCM-012, 8/14/02
User Fee date: 12/15/02 (4 months)

5. NAME OF THE DRUG
Actonel® tablets

6. NONPROPRIETARY NAME
Risedronate sodium

7. SUPPLEMENT PROVIDES FOR:
The addition of an alternate manufacturing site for Actonel 5 mg tablets.

8. AMENDMENTS/REPORT, DATE
8/15/02

9. PHARMACOLOGICAL CATEGORY
Treatment and prevention of osteoporosis. Treatment of Paget's disease of bone.

10. HOW DISPENSED
Rx

11. RELATED IND/NDA/DMF

12. DOSAGE FORM
Tablet

13. POTENCY
5 mg, 30 mg and 35 mg

14. CHEMICAL NAME AND STRUCTURE.
1-Hydroxy-1-phosphono-2-pyridin-3-yl-ethyl-phosphonic acid, monosodium salt, C₇H₁₀NO₇P₂Na₂.H₂O

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15. COMMENTS
This supplement is submitted to HFD-510 as a PA. The sponsor is proposing the use of the Procter & Gamble Pharmaceuticals Puerto Rico Inc. facility in Manati, PR as an alternate manufacturing site for Actonel 5 mg tablets. The amendment dated 8/15/02 informs the Agency that a field copy of this supplement was submitted to the Puerto Rico FDA district office. The supplement contains comparative dissolution data and site specific stability data (see chemist's review notes).

16. CONCLUSION AND RECOMMENDATION
From a chemistry standpoint, adequate information has been provided. Issue an approval letter.

17. NAME
Elsbeth G. Chikhale, Ph.D.

REVIEWER SIGNATURE

DATE COMPLETED
12/9/02

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Init. by:
CC: HFD-510, NDA 20-835/S-012
HFD-510/ S Markofsky / R Hedin / EG Chikhale/Division file/NDA 20-835
Page(s) Withheld

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

§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process
Establishment Inspection:

An EER was requested for the alternate facility and found acceptable. See attached EER summary report.

26-NOV-2002

Application: NDA 20835/012
Org Code: 510
Priority: 1S

Stamp Date: 15-AUG-2002
PDUFA Date: 15-DEC-2002
Action Goal: 10-NOV-2002
District Goal: 10-NOV-2002

Brand Name: ACTONEL (RISEDRONATE SODIUM)
3MG TABS

Generic Name: RISEDRONATE SODIUM
Dosage Form: TABLET
Strength: 5 MG

FDA Contacts: D. HEDIN Project Manager (HFD-510) 301-827-6392
E. CHIKHALE Review Chemist (HFD-820) 301-827-6420
S. MARKOFSKY Team Leader (HFD-510) 301-827-6420

Overall Recommendation: ACCEPTABLE on 16-SEP-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: CFN: 2650046
FBI: 2650046
PROCTER AND GAMBLE PHARMACEUTICALS PUERTO RICO INC
HWY 2 KM 457
MANATI, PR 00701

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE RELEASE TESTER
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE OTHER TESTER

Profile: TCM
OAI Status: NONE

Last Milestone: OC RECOMMENDATION
Milestone Date: 16-SEP-02
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Elisbeth Chikhale  
12/9/02 10:51:55 AM  
CHEMIST

Sheldon Markofsky  
12/10/02 07:44:19 AM  
CHEMIST
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-835/S012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
NDA 20-835/S-012

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-012

Date of Supplement: August 14, 2002

Date of Receipt: August 15, 2002

This supplement proposes Procter & Gamble Pharmaceuticals Puerto Rico, Inc., Manati, Puerto Rico, as an alternate manufacturing site for Actonel 5 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 October 14, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be December 15, 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
8/21/02 09:30:53 AM