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

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APPLICATION NUMBER:
NDA 20-835/S012

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
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Medical Review(s)	
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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-835/S012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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 you 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

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/s/

Sheldon Markofsky
12/10/02 02:59:48 PM

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APPLICATION NUMBER:

NDA 20-835/S012

CHEMISTRY REVIEW(S)

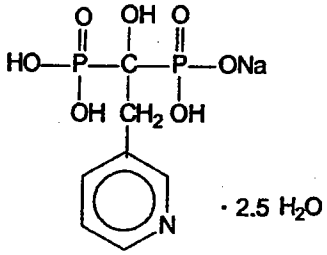
CHEMIST'S REVIEW	1.ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	20-835

3. NAME AND ADDRESS OF APPLICANT		4.SUPPLEMENT NUMBER,DATE
Procter & Gamble Pharmaceuticals, Inc. Health Care Research Center 8700 Mason Montgomery Road Mason, OH 45040-9462		SCM-012, 8/14/02 (PA) User Fee date: 12/15/02 (4 months)
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	
Actonel® tablets	Risedronate sodium	
7. SUPPLEMENT PROVIDES FOR:		8.AMENDMENTS/REPORT,DATE
The addition of an alternate manufacturing site for Actonel 5 mg tablets.		8/15/02

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11.RELATED IND/NDA/DMF
Treatment and prevention of osteoporosis. Treatment of Paget's disease of bone.	R_x	
12. DOSAGE FORM	13. POTENCY	
Tablet	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, $C_7H_{10}NO_7P_2Na.2.5H_2O$



15. COMMENTS

This supplement is submitted to HFD-510 as a PA. The sponsor is proposing the use of the Proctor & 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	REVIEWER SIGNATURE	DATE COMPLETED
Elsbeth G. Chikhale, Ph.D.		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

6 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

*Withheld Track Number: Chemistry-*20-835
S 012

Establishment Inspection:

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

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

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

Sponsor: PROCTER GAMBLE PHARM
11450 GROOMS RD
CINCINNATI, OH 452421434

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

Brand Name : ACTONEL (RISEDRONATE SODIUM) 30MG TABS
Estab. Name:
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-2002by J. D AMBROGIO(HFD-324) 301-827-0062

Establishment : CFN : 2650046 FEI : 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

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/s/

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

Sheldon Markofsky
12/10/02 07:44:19 AM
CHEMIST

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APPLICATION NUMBER:

NDA 20-835/S012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

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/s/

Randy Hedin
8/21/02 09:30:53 AM