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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-835/S011

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

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APPLICATION NUMBER:

NDA 20-835/S011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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 [redacted] 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

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/s/

Sheldon Markofsky
11/5/02 11:00:18 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

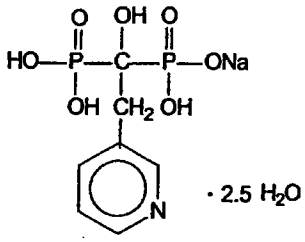
APPLICATION NUMBER:

NDA 20-835/S011

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. 8700 Mason Montgomery Road Mason, OH 45040-9462		SCP-011, 7/11/02 User Fee date: (PA supplement) 11/12/02 (4 months)
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	
Actonel® tablets	Risedronate sodium	
7. SUPPLEMENT PROVIDES FOR:		8.AMENDMENTS/REPORT,DATE
An alternate blister package for Actonel 35 mg tablets		
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 & 30 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

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 [redacted] 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:
CC: HFD-510, NDA 20-835/S-011, NDA 20-835/S-011
HFD-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

Withheld Track Number: Chemistry- 20-835
5011

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/s/

Elsbeth Chikhale
10/31/02 09:42:02 AM
CHEMIST

Sheldon Markofsky
10/31/02 02:07:23 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-835/S011

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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