CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-835/S010

Trade Name: Actonel Tablets

Generic Name: risedronate sodium

Sponsor: Proctor and Gamble Pharmaceuticals, Inc

Approval Date: September 26, 2002

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APPLICATION NUMBER:
NDA 20-835/S010

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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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Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

NDA 20-835/S010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-835/S-010

Procter and Gamble Pharmaceuticals, Inc.
Attention: Edwin O. Billips, RAC
Regulatory Affairs Manager
Health Care Research Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Mr. Billips:

Please refer to your supplemental new drug application dated April 12, 2002, received April 15, 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 an additional reprocessing procedure for the [redacted] of risedronate sodium that has [redacted] that exceed the regulatory acceptance criteria.

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
9/26/02 10:51:41 AM

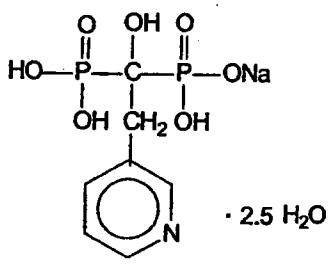
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-835/S010

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		SCS-010, 4/12/02 (CBE-30) User Fee date: 10/15/02 (6 months)
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	
Actonel® tablets	Risedronate sodium	
7. SUPPLEMENT PROVIDES FOR:		8.AMENDMENTS/REPORT,DATE
An additional reprocessing procedure [redacted] in the event that the drug substance exceeds the [redacted] specification at final testing.		
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 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 CBE-30. The sponsor is requesting an additional reprocessing procedure [redacted] in the event that the drug substance exceeds the [redacted] specification at final testing.		
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.		8/22/02
DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE		

Init. by:
CC: HFD-510, NDA 20-835/S-010
HFD-510/ S Markofsky / R Hedin / EG Chikhale/Division file/NDA 20-835

2 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

S010

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/s/

Elsbeth Chikhale
8/22/02 03:52:35 PM
CHEMIST

Sheldon Markofsky
8/23/02 08:06:25 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-835/S010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-835/S-010

CBE-30 SUPPLEMENT

Procter & Gamble Pharmaceuticals, Inc.
Attention: Edwin O. Billips, RAC, Regulatory Affairs Manager
Health Care Research Center
8700 Mason Montgomery Road
Mason, OH 45040-9462

Dear Mr. Billips:

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-010

Date of Supplement: April 12, 2002

Date of Receipt: April 15, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes an additional reprocessing procedure that will be used in synthesizing the drug substance. This additional reprocessing procedure provides for the [redacted] of risedronate sodium that has [redacted] values that are out of specification.

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 June 14, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 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: Division Document Room, 14B-19
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
4/22/02 03:17:37 PM