CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-835/S001-004

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
The Procter & Gamble Company Sharon Woods Technical Center 11450 Grooms Road Cincinnati, Ohio 4542-1434		SE1-001, 18-Dec.-1998 User Fee Date: N/A
5. NAME OF DRUG	6. NONPROPRIETARY NAME	
Actonel	Risedronate sodium	
		8. AMENDMENTS/REPORT, DATE
7. SUPPLEMENT PROVIDES FOR:		Amendment 12-17-99
1) A new 5 mg tablet for the treatment and prevention of Postmenopausal Osteoporosis and treatment Corticosteroid-Induced Osteoporosis 2) A robotic adaptation of the manual assay for all tablet strengths		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND/NDA/DMF
Treatment of Coticosteroid-Induced Osteoporosis	Prescription	NDA 20-835 NDA 20-835 SE1-002 NDA 20-835 SE1-003 NDA 20-835 SE1-004
12. DOSAGE FORM	13. POTENCY	DMF [redacted]
Tablets (oral)	5 mg, 30 mg (tablets)	[redacted]
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review # 1 of original NDA		
15. COMMENTS:		
The Chemistry review of this Prior Approval Efficacy Supplement, dated 7-12-99, granted a [redacted]-month expiry for the new 5mg tablets based on 24 months of satisfactory long term stability data. (Continued Next Page)		
16. CONCLUSION AND RECOMMENDATIONS		
From a Chemistry point of view, the proposed supplement is approvable. CSO: Please inform the applicant that a 36-month expiry is granted. Since the Chemistry issues related to this supplement apply equally to Efficacy Supplements 002, 003, and 004, these other supplements are also recommended for approval from a Chemistry point of view.		
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Sheldon Markofsky, Ph.D.	/S/	12-20-99
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R/D initialed by: /S/ 12-21-99 File name: [redacted]

15. COMMENTS (CONTINUED FROM PAGE 1):

In the amendment, dated 12-17-99, the applicant requested a 36-month expiry, based on up-dated 36 months of long term stability data. The data is satisfactory and a 36-month expiry is granted.

The cGMP compliance status for this NDA supplement is acceptable [EES, dated 12-17-99 (enclosed with hard copy).

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 20835/001**
Priority: **1S** Org Code: **510**
Stamp: **18-DEC-1998** Regulatory Due: **29-FEB-2000**
Action Goal: District Goal: **25-JAN-2000**
Applicant: **PROCTER GAMBLE PHARM**
ATTN: HARRY L WELLES
11450 GROOMS RD
CINCINNATI, OH 452421434
Brand Name: **ACTONEL (RISEDRONATE SODIUM) 30MG TABS**
Established Name:
Generic Name: **RISEDRONATE SODIUM**
Dosage Form: **TAB (TABLET)**
Strength: **5 MG**

FDA Contacts:

D. HEDIN	**(HFD-510)**	**301-827-6392**	**, Project Manager**
S. MARKOFSKY	**(HFD-510)**	**301-827-6420**	**, Review Chemist**
D. WU	**(HFD-510)**	**301-827-6375**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 02-DEC-1999 by M. EGAS (HFD-322) 301-594-0095

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **13-MAY-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**
Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

Establishment: [redacted]
DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **04-JAN-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: **FINISHED DOSAGE PACKAGER**

Establishment: [redacted]
DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **04-JAN-1999**
Responsibilities: **FINISHED DOSAGE PACKAGER**

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: [redacted]

DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE PACKAGER**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **04-JAN-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: **9615725**
PROCTER & GAMBLE PHARMACEU
1 CHEMIN DE SAULXIER
LONGJUMEAU, , FR 91160

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE RELEASE TESTER**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **02-DEC-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: **1313411**
PROCTER AND GAMBLE PHARMACI
WOODS CORNERS
NORWICH, NY 13815

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE OTHER TESTER**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **04-JAN-1999**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: **1350044**
PROCTER AND GAMBLE PHARMACI
RT 12
NORTH NORWICH, NY 13814

DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE** Responsibilities: **FINISHED DOSAGE**

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

MANUFACTURER

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **02-JUN-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: **9611632**
PROCTOR AND GAMBLE PHARMAC
DR OTTO ROHM STRASSE 2-4
WEITERSTADT, DARMSTADT, GM

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-JAN-1999**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE RELEASE TESTER**

APPEARS THIS WAY
ON ORIGINAL

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

3. NAME AND ADDRESS OF APPLICANT	4. SUPPLEMENT NUMBER, DATE
The Procter & Gamble Company Sharon Woods Technical Center 11450 Grooms Road Cincinnati, Ohio 4542-1434	SE1-001, 18-Dec.-1998 User Fee Date: 6-18-99

5. NAME OF DRUG	6. NONPROPRIETARY NAME	8. AMENDMENTS/REPORT, DATE
Actonel	Risedronate sodium	

7. SUPPLEMENT PROVIDES FOR:	8. AMENDMENTS/REPORT, DATE
1) A new 5 mg tablet for the treatment and prevention of Postmenopausal Osteoporosis and treatment Corticosteroid-Induced Osteoporosis 2) A robotic adaptation of the manual assay for all tablet strengths	Amendment 3-29-99 Amendment 7-7-99 Correspondence 1-22-99

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND/NDA/DMF
Treatment of Coticosteroid-nduced Osteoporosis	Prescription	NDA 20-835 NDA 20-835 SE1-002 NDA 20-835 SE1-003

12. DOSAGE FORM	13. POTENCY	DMF
Tablets (oral)	5 mg, 30 mg (tablets)	

14. CHEMICAL NAME AND STRUCTURE

See Chemistry Review # 1 of original NDA

15. COMMENTS:

This Prior Approval Efficacy Supplement was given a Priority Review status. The supplement, for the treatment and prevention of Postmenopausal Osteoporosis and treatment Corticosteroid-Induced Osteoporosis, provides for a new strength of Actonel (tablets). (Continued Next Page)

16. CONCLUSION AND RECOMMENDATIONS

From a Chemistry point of view, the proposed supplement is approvable pending a satisfactory CGMP inspection report. CSO: Please inform applicant that only — month expiry is granted at this time.

17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Sheldon Markofsky, Ph.D.	/S/	7-12-99

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R/D initialed by: /S/ File name: 7/12/99

15. COMMENTS (CONTINUED FROM PAGE 1):

Additionally the supplement provides for a robotic adaptation of the manual assay for Actonel (Tablets). [The new tablet strength and the robotic assay will also apply to two other Efficacy Supplements (SE1-002 and SE1-003), that are currently under review.]