CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020835

ADMINISTRATIVE DOCUMENTS

Patent Information Statement Pursuant to 21 USC 355(b)

The drug for which this application is submitted is claimed in U.S. Patent 5,583,122, issued December 10, 1996, assigned to The Procter & Gamble Company (the parent company of Procter & Gamble Pharmaceuticals, Inc.) This patent expires December 10, 2013.

Procter&Gamble

The Procter & Gamble Company
Sharon Woods Technical Center
11450 Grooms Road, Cincinnati, Ohio 45242-1434

September 26, 1997

Solomon Sobel, M.D., Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Attention: Document Control Room 14B-19
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: NDA # 20-835, ACTONEL (risedronate sodium), Treatment of Paget's Disease of Bone
NDA Amendment 4: Request to Withdraw Environmental Assessment
Minor Corrections to CMC Section of NDA #20-835

Dear Dr. Sobel:

As discussed with Mr. Randy Hedin, CSO on 6 August 1998, Procter & Gamble Pharmaceuticals wishes to withdraw the Environmental Assessment submitted as part of NDA #20-835 (V1.005, p326) and request a categorical exclusion from the requirement based on the recent revision to 21 CFR 25.31(b) [29 July 1997 Federal Register Notice]. The request for the exclusion is provided in Attachment 1.

We would also like to correct two minor errors in the CMC section of this NDA. These are:

1. A correction to the dilution volume in the analysis of cyclic dimer and related impurities (V1.004, p. 39). The volume was incorrectly stated as 1000 ml. The correct volume is 500 ml.
2. A correction to the storage statement provided in the NDA stability amendment (V2.001, p. 121). In order to be consistent with the proposed labeling, the statement should say "Store at controlled room temperature 20°-25°C (68°-77°F) [See USP]."

Details of both corrections are provided in Attachment 2 and a full copy of the corrected analytical method is in Attachment 3. Please contact me if there are any questions and/or clarifications regarding this NDA amendment.

Sincerely,

APPEARS THIS WAY
ON ORIGINAL

Hina S. Wu, Pharm.D.
Senior Scientist
US Regulatory Affairs
Phone: (513) 626-1190
FAX: (513) 626-1386

Desk Copy: Dr. Sheldon Markofsky, Chemistry Reviewer
Mr. Randy Hedin w/o attachments

EXCLUSIVITY SUMMARY for NDA # 20-835 **SUPPL #** —

Trade Name Actonel **Generic Name** Risedronate Sodium

Applicant Name Procter & Gamble **HFD-** 510

Approval Date _____

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

   a) Is it an original NDA?

   YES /✓/ NO /___/

   b) Is it an effectiveness supplement?

   YES /___/ NO /___/

   If yes, what type? (SE1, SE2, etc.) _____

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

   YES /✓/ NO /___/

   If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

   _____

   _____

   If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

   _____

   _____

d) Did the applicant request exclusivity?

YES /✓/ NO /___/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

5 years

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use?

YES /___/ NO /✓/

If yes, NDA # _____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /✓/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

APPEARS THIS WAY
ON ORIGINAL

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /✓/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /___/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

   For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

   (a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:**

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # _____

Investigation #2, Study # _____

Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #__, Study # _____

Investigation #__, Study # _____

Investigation #__, Study # _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1	
IND # _____ YES /___/	NO /___/ Explain: _____
	_____
Investigation #2	
IND # _____ YES /___/	NO /___/ Explain: _____
	_____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1	
YES /___/ Explain _____	NO /___/ Explain _____
_____	_____
_____	_____

Investigation #2

YES /___/ Explain _____ | NO /___/ Explain _____

_____ | _____

_____ | _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

_____

_____

APPEARS THIS WAY

/S/

_____ 2/9/98

Signature Date

Title: Senior Reg. Mgmt. Officer

/S/

_____ 3/10/98

Signature of Division Director Date

APPEARS THIS WAY

cc: Original NDA Division File HFD-85 Mary Ann Holovac

Exclusivity Statement

Requesting Five Years of Exclusivity

As part of this new drug application, Procter & Gamble Pharmaceuticals (P&GP) is requesting five years exclusivity for the use of ACTONEL (risedronate sodium) in the treatment of Paget's disease of bone. P&GP is the sole developer of this new chemical entity and owns the patent rights.

Pursuant to §§ 314.50(j) and 314.108(b)(2), support for this exclusivity request is based on the following:

1. To the best of P&GP's knowledge or belief, the active moiety risedronate sodium is a new chemical entity which has not been approved by the Food & Drug Administration in any other drug product either as a single entity or as part of a combination product.

2. To the best of P&GP's knowledge or belief, the active moiety risedronate sodium has not previously been marketed in the United States under any name.

APPEARS THIS WAY
ON ORIGINAL

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

NDA/BLA # 20-835 Supplement # _____ Circle one: SE1 SE2 SE3 SE4 SE5 SE6

HFD-510 Trade and generic names/dosage form: Actonel (risedronate) Action: (AP) AE NA

Applicant Procter & Gamble Therapeutic Class 15

Indication(s) previously approved None

Pediatric information in labeling of approved indication(s) is adequate ✓ inadequate __

Proposed indication in this application Treatment of Paget's disease of bone

FOR SUPPLEMENTS, ANSWER THE FOLLOWING QUESTIONS IN RELATION TO THE PROPOSED INDICATION.

IS THE DRUG NEEDED IN ANY PEDIATRIC AGE GROUPS? ___Yes (Continue with questions) ___No (Sign and return the form)

WHAT PEDIATRIC AGE GROUPS IS THE DRUG NEEDED? (Check all that apply)

__Neonates (Birth-1month) __Infants (1month-2yrs) __Children (2-12yrs) __Adolecents(12-16yrs)

__ 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.

__2. **PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

__ 3. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use.

__ a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.

__ b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.

__ c. The applicant has committed to doing such studies as will be required.

__ (1) Studies are ongoing,

__ (2) Protocols were submitted and approved.

__ (3) Protocols were submitted and are under review.

__ (4) If no protocol has been submitted, attach memo describing status of discussions.

__ d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

X 4. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed. – Memo - It is not used in children.

__ 5. **If none of the above apply, attach an explanation, as necessary.**

ARE THERE ANY PEDIATRIC PHASE IV COMMITMENTS IN THE ACTION LETTER? ___ Yes X No

ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

This page was completed based on information from Medical Review (e.g., medical review, medical officer, team leader)

P.M. 2/26/98

Signature of Preparer and Title Date

cc: Orig NDA/BLA # 20-835
HFD-510 /Div File
NDA/BLA Action Package
HFD-006/ KRoberts

(revised 10/20/97)

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT, KHYATI ROBERTS, HFD-6 (ROBERTSK)

Debarment Certification

Certification Pursuant to the Generic Drug Enforcement Act of 1992

Pursuant to 21 USC §355a(k)1, Procter & Gamble Pharmaceuticals hereby certifies it has not and will not use in any capacity the services of any person debarred under subsection 21 USC §355a(a or b), in connection with this New Drug Application.

Respectfully submitted,

Larry R. Versteegh, Ph.D.
Vice President
Regulatory Affairs Worldwide
Procter & Gamble Pharmaceuticals

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

MAR 10 1998

NDA 20835
Draft Labeling
Response and Comments

Proctor & Gamble
Comments from Jayne Peterson
10 March, 1998

There are a few of the comments that I believe require some input from DMEDP as follows:

CLINICAL STUDIES: There were 6 studies that P & G wanted to mention. Since only one of them was blinded and controlled with etidronate, and one was open and controlled by low doses of drug, while others were not adequately controlled, we allowed them only to mention those 2 studies. However, the low dose study was short and small (62 patients in 3 dose groups for 28 days) and yielded little data that was of value for the label. Yes, data from the single study only might be used.

"Normalization" was to bring total SAP to within the normal range for the laboratory. "Normal" values for SAP may vary with the laboratory.

The label gives the per cent of patients in each group who have not relapsed as though they were comparable even though residronate was discontinued at 60 days and etidronate at 180 days, because those are the durations of treatment that are recommended. The fact that a patient can take residronate for only 60 days and remain controlled for the full 180 days is a selling point for the drug. The Peterson comments have it backward; etidronate was taken for 6 months and residronate 2 months in this study.

You are quite right about demographics. Sixty per cent of subjects were over 65 years old (commensurate with the distribution of the disease). Seventy per cent were men (commensurate with the distribution of the disease). Over 90% were caucasian.

Pagetic and non-pagetic patients are patients with and without pagetic lesions and therefore a diagnosis of Paget's disease of bone. Non-pagetic bone is bone that is from or in an area of bone not involved with a pagetic lesion, and may be found in patients with or without Paget's disease of bone. The lesions in bone which characterize Paget's disease are holes and places of excess formation of bone that is abnormal. The holes tend to fill in with treatment, but do not go away. The diagnosis of the disease is not dependent upon the response to treatment.

/S/

Gloria Troendle

Memorandum of Telecon

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Clinical Pharmacology and Biopharmaceutics

Date of Telecon:	12/08/97
From:	Robert M. Shore /S/ DEC - 8 1997
Re:	Actonel (risedronate) NDA 20-835/N-000
Participants:	Robert M. Shore (FDA); Hena Wu, Dave Mitchell, Gary Thompson (P&GP)

1) I asked the sponsor to supply validation data for the PCNONLIN modeling which they undertook in a number of studies. Specifically, I requested a table for each of five studies (RRF, 1994022, RSD, RAB, and RRI) that would list the following: Subject, Cmax fitted, Cmax observed, Tmax fitted, Tmax observed, AUC0-t fitted, AUC0-t observed. This would allow a quick comparison of the fitted and observed results as well as a comparison of the fitted data to pharmacokinetic parameter estimates from other studies that were generated with the The sponsor responded that, according to a June 17, 1996 meeting (Vol1.001/p59), Dr. Ahn had stated that the use of both serum and urine data was acceptable and they were not sure why there was a need for this validation comparison to be done. I explained that I am not questioning the method but rather that I am asking for validation; Dr. Ahn's remarks stand on their own and my asking for validation of their method is commonplace. The sponsor stated that such a comparison could readily be submitted for 1994022 but that it would take time to generate such a comparison for other studies. They also felt that repeating such an analysis for all five studies was unnecessary because the same model was used in all the studies - it was validated once in 1994022. I stated that I would confer with Dr. Carolyn Jones (co-reviewer) and Dr. Ahn (team leader) regarding the need for all five studies to be analyzed or if only the one study would suffice.

2) I asked that the sponsor address the following inconsistencies between studies 92016 and RAB. They stated that they will need time to examine the data and submit a response.

a) Intra- and inter-subject variability (CV%) in pharmacokinetic parameters was determined for each of these studies. However, the estimates from the two studies were different and I asked the sponsor to supply a reason why.

b) The Cmax from study 92106 (10 mg single-dose) and study RAB (30 mg single-dose) was about the same when I would expect there to be a 3-fold increase with the 30 mg dose. I asked the sponsor why the Cmax seemed to be the same with different doses.

3) I had previously asked if there was an assay stability data in the CANDA since I could not find any. My concern was that there should be some indication that serum and urine samples collected and frozen are actually stable under these conditions. I was told that there maybe stability data in the submission and the sponsor would get back to me and let me know where to find it. There was also mention of ongoing stability work and references.

CC: NDA 20-835/N-000(orig., 1 copy), HFD-510(Hedin), HFD-870(Shore, Jones, Ahn), CDR(Murphy)

Memorandum of Telecon

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Clinical Pharmacology and Biopharmaceutics

DEC - 1 1997

/S/

Date of Telecon:	12/01/97
From:	Robert M. Shore
Re:	Telecon about NDA 20-835 Actonel (risedronate)
Participants:	Robert M. Shore (FDA); Hina Wu, Harry Wells, Dave Mitchell (P&GP)

In this teleconference, I was informed of the following:

1) The three 10 mg capsules listed on Vol1.002/p57-58 are manufactured with essentially the same process - all use a dry blend and the same equipment.

2) The various strengths of the tablet formulations listed in Vol1.002/p62-64 are manufactured with the same process.

CC: NDA 20-835/N-000 (orig., 1 copy), HFD-510(Hedin), HFD-870 (Shore, Jones)

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

RECORD OF TELEPHONE CONVERSATION/MEETING	DATE: 11/21/97 NOV 24 1997
I called to get clarification of the following questions: 11/19/97 1. The pre-NDA meeting package for the sNDA for Actonel for osteoporosis states that two carcinogenicity studies were already submitted in the Actonel original NDA. Which studies were these? **Response:** The reports submitted were 1 year interim reports from the 2-year carcinogenicity studies, not full reports of the studies as indicated. Full reports will be in the sNDA. 2. Was the dose selection presented to and accepted by the FDA-CAC? Will you provide justification of dose selection in the sNDA. **Response:** The doses were approved by the CAC for the second rat and the one mouse study. Sponsor will FAX copies of this correspondence and include rationale for the dose selection and copies of correspondence in the sNDA and in preparation for the CAC review of the study results. 11/21/97 1. PK is not dose-linear in animals. Over what range of doses is AUC dose-linear in humans? **Response:** PK was determined only for the range of doses used in the clinical trial. It was found to be linear over this range. No parameters were measured at higher doses. 2. What is the PK like in Paget's patients vs. normal humans? **Response:** PK was not measured in patients. Internal comment: I am concerned that: 1) We do not know the level of exposure in patients. 2) The exposure in humans could be non-linearly related to dose at doses only slightly higher than the prescribed dose. Are these clinical concerns? From the pharmacology viewpoint, this lack of information makes data about animal toxicity at (n) multiples of human exposure levels rather meaningless. The same (n) multiples of dose levels are not necessarily linearly related to exposure in patients or even in normal controls.	**NDA/IND NUMBER:** NDA: #20-835 **PRODUCT NAME:** Actonel **FIRM NAME:** Procter & Gamble **NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD:** Hina Wu, Pharm.D.Regulatory Page Smith, PhD. Toxicology Dave Mitchell, Clin. PK Gary Thompson, Clin PK **TELEPHONE NUMBER:** (513) 626-1190
SIGNATURE: /S/ Daniel T. Coleman, Ph.D. Pharmacologist	**DIVISION:** DMEDP

11/21/97

cc:

HFD510

HFD510/Dutta/Lutwak/Ahn/Steigerwalt/DColeman/Hedin

NDA 20-835

APR 7 1997

Procter and Gamble Pharmaceuticals
Attention: Hina Wu, Pharm.D.
Senior Scientist, Regulatory Affairs
11450 Grooms Road
Cincinnati, OH 45242

APPEARS THIS WAY
ON ORIGINAL

Dear Dr. Wu:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Actonel (risedronate sodium) Tablet 30 mg
Therapeutic Classification:	Standard
Date of Application:	March 31, 1997
Date of Receipt:	April 1, 1997
Our Reference Number:	20-835

APPEARS THIS WAY
ON ORIGINAL

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 May 31, 1997 in accordance with 21 CFR 314.101(a).

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone. Should you wish a conference, a telephone report, or if you have any questions concerning this NDA, please contact Randy Hedin, R.Ph., Consumer Safety Officer, at (301) 443-3520.

APPEARS THIS WAY
ON ORIGINAL

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

Sincerely yours,

4-7-97

APPEARS THIS WAY
ON ORIGINAL

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

4/7/97

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-835
HFD-510/Div. Files
HFD-510/CSO/R.Hedin
HFD-510/SDutta/GTroendle/DWu/GKuijpers/RSteigerwalt/HAhn/DMarticello
DISTRICT OFFICE

Drafted by: RH/April 4, 1997/N20835AC.LT1
Final:

ACKNOWLEDGEMENT (AC)

APPEARS THIS WAY
ON ORIGINAL