CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020835

APPROVAL LETTER

NDA 20-835

MAR 27 1998

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

APPEARS THIS WAY
ON ORIGINAL

Dear Dr. Wu:

Please refer to your new drug application dated March 31, 1997, received April 1, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actonel (risedronate sodium) 30 mg Tablets.

We acknowledge receipt of your submissions dated April 16, July 25 and 31, September 26, October 14 and 16, and December 5, 10, 12, 18, and 19, 1997; and January 6, 7, and 16, February 10, 13, 18, 20, 23, and 24, and March 2, 4, and 12, 1998. The User Fee goal date for this application is April 1, 1998.

This new drug application provides for the treatment of Paget's disease of bone.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated March 12, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft patient package insert submitted on March 12, 1998, and draft packaging labeling dated March 10, 1998. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING for approved NDA 20-835." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

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Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, please contact Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301)827-6392.

Sincerely yours,

APPEARS THIS WAY
ON ORIGINAL

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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ON ORIGINAL

cc:
Original NDA 20-835
HFD-510/Div. files
HFD-510/CSO/R.Hedin
HFD-510/GTroendle/GKuijpers/DColeman/RSteigerwalt/CJones/HAhn

/SMarkofsky/DWu/JMele
HFD-002/ORM (with labeling)
HFD-102/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-715/JMele
HFD 870/CJones/HAhn
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)

Drafted by: RH/February 26, 1998/N20835AP.LT1
Initialed by: Gtroendle3.3/DColeman3.2/GKuijpers/Rsteigerwalt/SMarkofsky
/DWu/3.6/RShore/CJones/3.4/HAhn3.5/LPian/EGalliers3.9/SSobel3.15.98
final:

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.