# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number: 020819**

**Trade Name: ZEMPLAR**

**Generic Name: PARICALCITOL INJECTION**

**Sponsor: ABBOTT LABORATORIES**

**Approval Date: 04/17/98**

**INDICATION(s): FOR THE PREVENTION AND TREATMENT OF SECONDARY HYPERPARATHYROIDISM ENCOUNTERED WITH CHRONIC RENAL FAILURE.**

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## APPLICATION: 020819

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| | Included | Pending Completion | Not Prepared | Not Required |
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| Approval Letter | X | | | |
| Tenative Approval Letter | | | | X |
| Approvable Letter | | | | X |
| Final Printed Labeling | | X | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | X | | | |
| EA/FONSI | | | | X |
| Pharmacology Review(s) | X | | | |
| Statistical Review(s) | X | | | |
| Microbiology Review(s) | X | | | |
| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
| Bioequivalence Review(s) | | | | X |
| Administrative Document(s)/ Correspondence | X | | | |

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**Application Number: 020819**

## APPROVAL LETTER

NDA 20-819

Abbott Laboratories
Attention: Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road, D-389 AP30
Abbott Park, IL 60064-3537

APR 17 1998

Dear Dr. Willer:

Please refer to your new drug application dated January 17, 1997, received January 17, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemplar (paricalcitol injection).

We acknowledge receipt of your submissions dated January 31, April 4 and 18, May 30, June 13 and 20, August 1(2), 15, and 29, September 3, October 1, 21, 22, 24, 29, and 31(2), and December 10, 1997; and January 23, February 25, March 3(2), 5, 12, 20, 23(2), 24, 26, and 27, and April 3, 7(2), 9, 16, and 17, 1998. The original User Fee goal date for this application was January 17, 1998. Your submission of October 31, 1997, extended the User Fee goal date to April 17, 1998.

This new drug application provides for the use of Zemplar Injection for the prevention and treatment of secondary hyperparathyroidism encountered with chronic renal failure.

We have completed the review of this application, as amended, 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. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft physician package insert dated April 17, 1998, and the draft carton and container labeling dated April 7, 1998, as revised April 17, 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 20-819. Approval of this submission by FDA is not required before the labeling is used.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. For Phase 4 commitments not requiring an IND, submit protocol, data, and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii) we request that you include a status summary of each commitment in your annual report to this application. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments should be clearly designated "Phase 4 Commitments."

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

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., Regulatory Management Officer, at (301)827-6392.

Sincerely yours,

/S/

4/17/98

APPEARS THIS WAY
ON ORIGINAL

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

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-819
HFD-510/Div. files
HFD-510/CSO/R.Hedin
HFD-510/LLutwak/GTroendle/SMarkofsky/DWu/DColeman/RSteigerwalt/CJones/HAhn
/BElashoff/ENevius/SSobel/EGalliers
HFD-002/ORM (with labeling)
HFD-102/Office Director
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/LPian
HFD-870/CJones/HAhn
HFI-20/Press Office (with labeling)

APPEARS THIS WAY
ON ORIGINAL

Drafted by: RH/April 7, 1998/N20819AP.LT1
Initialed by:JMele/4.8/LLutwak/GTroendle/RSteigerwalt/DWu/HAhn/SSobel/4.9.98
final:

APPROVAL (AP) [with Phase 4 Commitments]