NDA 21-068 20 November 1998
NDA 18-044/S-025

Hoffman LaRoche
Attention: Mr. Anthony Corrado
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Mr. Corrado:

Please refer to your new drug application (NDA) and your supplemental new drug application dated November 18, 1997, received November 20, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rocaltrol (calcitriol) 1 mcg/mL oral solution (NDA 21-068) and 0.25 and 0.50 mcg capsules (NDA 18-044/S-025), respectively.

We acknowledge receipt of your submissions dated February 13 (2) and 17, March 6, April 30, July 15 and 21, September 1, October 27, and November 2, 12, 19, and 20 (2), 1998. We also acknowledge a third submission dated November 20, 1998, to NDA 21-068 only.

This new drug application (NDA 21-068) provides for a new oral solution dosage form for the treatment of secondary hyperparathyroidism in patients (including pediatric patients) with moderate to severe chronic renal failure (creatinine clearance of 15 to 55 mL/min) who are not yet undergoing dialysis.

This supplemental new drug application (capsules; NDA 18-044/S-025) provides for the new indication of the treatment of secondary hyperparathyroidism in patients (including pediatric patients) with moderate to severe chronic renal failure (creatinine clearance of 15 to 55 mL/min) who are not yet undergoing dialysis.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted labeling text. Accordingly, the applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling text for the package insert , the immediate container label (oral solution), and the carton label (oral solution) dated November 20, 1998. Marketing the product with FPL that is not identical to the approved labeling text 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 "FPL for approved NDA 21-068 and NDA 18-044/S-025."

Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated November 12, 1998. These commitments, along with any completion dates agreed upon, are listed below.

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 21-068. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. 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 must be clearly designated “Phase 4 Commitments."

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

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

Please submit one market package of the oral solution 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 Ms. Jena Weber, Project Manager, at (301) 827-6422.

Sincerely,

/s

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research