DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-044/S-032
NDA 21-068/S-002

Hoffmann-La Roche Inc.
Attn: Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias;

Please refer to your supplemental new drug applications dated January 12, 2004, received January 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 18-044, Rocaltrol (calcitriol) Capsules and NDA 21-068, Rocaltrol (calcitriol) Oral Solution.

These supplemental new drug applications provide for revisions to the WARNINGS, ADVERSE REACTIONS, and OVERDOSAGE sections of the package insert (PI) for Rocaltrol. They also propose adding a new ANIMAL TOXICOLOGY section to this PI, which is identical for the Rocaltrol Capsules and Oral Solution.

We completed our review of these applications. The applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

- Eliminate the proposed ANIMAL TOXICOLOGY section since the information in this section does not provide identification or quantification of a specific clinical safety concern.

We note that in a telephone conversation on June 23, 2004, between you and Ms. Pat Madara, project manager from this division, you agreed to delete this text.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the submitted labeling (package insert submitted January 12, 2004). These revisions are terms of the approval of these applications.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format – NDAs* (January, 1999) and draft guidance *Providing Regulatory Submissions in Electronic Format – Content of Labeling* ((February 2004). The guidances specify labeling to be submitted in *pdf* format. **To assist in our review, we request that labeling also be submitted in MS Word format**.

If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper**.** For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 18-044/S-032 or NDA 21-068/S-002." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks
7/7/04 12:15:10 PM
for Dr. Orloff