



NDA 18044/S-038

SUPPLEMENT APPROVAL

Validus Pharmaceuticals LLC
Attention: Elizabeth Fenna, Regulatory Affairs
119 Cherry Hill Road, Suite 310
Parsippany, NJ 07054

Dear Ms. Fenna:

Please refer to your supplemental new drug application dated September 3, 2009, received September 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rocaltrol (calcitriol) 0.25 mcg and 0.50 mcg capsules.

This "Changes Being Effected" supplemental new drug application provides for changes to the container and shipper labels for the 0.25 mcg (30- and 100- count) and 0.50 mcg (100-count) presentations.

We have completed our review of this application. It is approved, effective on the date of this letter, for use with these approved products,

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your September 3, 2009 submission containing final printed container and shipper labels and find them acceptable.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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, please call Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure(s)
Container Labeling

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-18044

SUPPL-38

VALIDUS
PHARMACEUTICA
LS LLC

Rocaltrol (calcitriol) Capsules

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

/s/

MARY H PARKS

02/22/2010