DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-468/ S-010

Shire Development Inc.
Attention: Michael McGraw
Senior Associate, Regulatory Affairs
725 Chesterbrook Blvd
Wayne, PA 19087-5637

Dear Dr. McGraw:

Please refer to your supplemental new drug application dated December 6, 2007, received December 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosrenol (lanthanum carbonate) 500 mg, 750 mg and 1000 mg chewable tablets and the sample pack for the 1000 mg strength tablets.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. The phrase, "TAKE WITH OR IMMEDIATELY AFTER MEALS" appears more prominently on the front and back panels of the Fosrenol patient carton and in small print on the side panel of the carton.
2. The phrase, "TAKE WITH OR IMMEDIATELY AFTER MEALS" has been added to the individual patient container label and sample container label.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the carton and container labeling submitted on December 6, 2007.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 call Anna Park-Hong, Regulatory Project Manager, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

Norman Stockbridge

4/10/2008 10:32:09 AM