DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-468/S-011

Shire Development Inc.
Attention: Valerie Waltman
725 Chesterbrook Blvd.
Wayne, PA 19087-5637

Dear Ms. Waltman:

Please refer to your supplemental new drug application dated April 22, 2008, received April 22, 2008, 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.

This supplemental new drug application provides for revisions to both the **Information for the Patient** and the **DOSAGE AND ADMINISTRATION** sections of the label.

You proposed the following revisions:

1. In the **Information for the Patient** section, the sentence "To aid in chewing, tablets may be crushed" has been added after the third sentence of the first paragraph.

2. In the **DOSAGE AND ADMINISTRATION** section, the second sentence of the first paragraph has been changed from:

   "The recommended initial total daily dose of Fosrenol is 750 mg."

   To:

   "The recommended initial total daily dose of Fosrenol is 1500 mg."

3. In the **DOSAGE AND ADMINISTRATION** section, the sentence "To aid in chewing, tablets may be crushed" has been added after the first sentence in the third paragraph

Other proposed changes include minor editorial changes to the **HOW SUPPLIED** section.

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 agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the text for the package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-468/S-011**."

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
Suite 12B05
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, please call:

Lori Wachter
Regulatory Project Manager
(301) 796 3975

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

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