



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-693

Roxane Laboratories, Inc.
Attention: Elizabeth Ernst
Director, Drug Regulatory Affairs
1809 Wilson Road
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 27, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Calcium Acetate Tablets USP, 667 mg (equivalent to 169 mg Calcium).

Reference is also made to your amendments dated July 28, 2005; and March 24, and May 15, 2006; and November 16, 2007.

The reference listed drug (RLD) upon which you have based your ANDA, PhosLo Tablets, 667 mg, of Fresenius Medical Care North America (Fresenius), ceased marketing in the United States. As a result, Fresenius' PhosLo Tablet was moved to the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). In a Federal Register Notice issued on July 31, 2007 (Docket Nos. 2006P-0287 and 2006P-0399), the agency announced its determination that PhosLo Tablets, 667 mg, was not withdrawn from sale for reasons of safety or effectiveness. With this determination having been made, the agency may continue to approve ANDAs that reference PhosLo Tablets, 667 mg. See 21 CFR 314.161.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Calcium Acetate Tablets USP, 667 mg (equivalent to 169 mg Calcium) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, PhosLo

Tablets, 667 mg, of Fresenius Medical Care North America. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
1/30/2008 01:35:01 PM
for Gary Buehler