DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-728

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 May 27, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Calcium Acetate Capsules, 667 mg (equivalent to 169 mg Calcium).

Reference is also made to the tentative approval letter issued by this office on November 30, 2007, and your amendments dated July 28, and November 15, 2005; March 24, and May 16, 2006; and January 15, 2008.

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 Capsules, 667 mg (equivalent to 169 mg Calcium), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, PhosLo GelCaps, 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 ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, PhosLo GelCaps, 667 mg, of Fresenius Medical Care North America (Fresenius), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,576,665 (the '665 patent), is scheduled to expire on April 3, 2021.

Your ANDA contains a paragraph IV certification to the '665 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Calcium Acetate Capsules, 667 mg (equivalent to 169 mg Calcium), under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Roxane Laboratories, Inc. (Roxane) for infringement of the '665 patent. This action must have been brought against Roxane prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Roxane complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Roxane for infringement of the '665 patent in the United States District Court for the Southern District of Ohio, Eastern Division [Fresenius Medical Care North America v. Roxane Laboratories, Inc., Civil Action No. C2 05 889]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, the agency has concluded that Roxane was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '665 patent. Therefore, with this approval, Roxane is eligible for 180-days of generic drug market exclusivity for Calcium Acetate Capsules, 667 mg (equivalent to 169 mg Calcium). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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 application 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 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
2/26/2008 10:45:01 AM
for Gary Buehler