DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 40-541

Food and Drug Administration
Rockville MD 20857

NOV 12 2004

PharmaForce, Inc.
Attention: Marilyn A. Friedly
U.S. Agent for: Bioniche Pharma U.S.A. Inc.
1507 Chambers Road
Columbus, OH 43212

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sotradecol® Injection (Sodium Tetradecyl Sulfate Injection), 1% (10 mg/mL) and 3% (30 mg/mL), packaged in 2 mL vials.

Reference is also made to your amendments dated July 22 and September 3, 2003; and July 13, August 25, September 30, and October 20, 2004.

This ANDA was granted "Expedited Review" status by the Center director because there is a nation-wide shortage of this medically necessary drug product.

We note that the reference listed drug product (RLD) upon which you have based this application, Sotradecol Injection of Elkins Sinn, is no longer being marketed in the United States. Thus, Elkins Sinn's Sotradecol Injection currently appears in the Discontinued section of the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". Reference is made to the Federal Register notice dated November 7, 2002 (Volume 67, No. 216) in which the Agency announced its determination that Elkin Sinn's Sotradecol Injection, 1% and 3%, was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the Agency to approve ANDAs for the discontinued drug product.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has

determined your Sotradecol® Injection (Sodium Tetradecyl Sulfate Injection), 1% and 3%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Sotradecol® Injection, 1% and 3%, respectively, of Elkins Sinn, a Division of A. H. Robbins Co., Inc.).

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

Post-marketing reporting requirements for this abbreviated 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(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

(b)(6)

Sincerely yours,

(b)(6)

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research