DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER
NWE-18-06W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 24, 2006

Thomas H. Faria, President
Sheffield Laboratories, Div. of Faria Limited, LLC.
170 Broad Street
New London, CT 06320-5313

Dear Mr. Faria:

An inspection of your drug manufacturing facility located at 170 Broad Street, New London, CT, conducted by a Food and Drug Administration (FDA) investigator and analyst on October 17-19, 2005, found significant deviations from FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations (CFR) Part 211. Failure to conform to the CGMP regulations cause products manufactured by your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(a)(2)(B). Our investigator found the following significant deviations from the CGMPs for finished pharmaceuticals:

1. Failure of the Quality Control Unit (QCU) to have adequate written procedures, as required by 21 CFR 211.22(d). For example, your firm does not have procedures to ensure that product failures, failure investigation results, out-of-specification (OOS) results, and stability failures are communicated to clients with whom you contract to manufacture their products.

2. Failure of your QCU to be responsible for approving all procedures and specifications impacting on the identity, strength, quality, and purity of drug products, as required by 21 CFR 211.22(c). The products you manufacture for other firms are sent to contract laboratories for testing. However, your QCU did not review or approve the analytical methods used to analyze

the Debriding Ointment, Cervical Cream, Lidocaine Hydrochloride, Hydrocortisone Acetate, and Capsaicin products, nor did the QCU assure that these methods were properly validated. For these products, you do not have any documentation or raw data for the validation of the analytical methods used by your contract testing laboratories, nor do you have any certification or written assurance from the contract testing laboratories stating that only validated analytical methods are used. In addition, the same observation was cited at the conclusion of the 2004 inspection for Lidocaine Hydrochloride.

3. Failure to conduct a thorough investigation and maintain written records of the investigation of the failure of a batch or any of its components to meet any of its specifications as required by 21 CFR 211.192. In addition, you failed to follow SOP #515-03, Investigation of Out of Specification Results. For example, you failed to thoroughly investigate and document 1) stability testing failures of Cypress Papain Urea Chlorophyllin Debriding Ointment finished product, lot numbers 1F103 and 1F104; 2) follow-up stability testing failures for the same drug product, lot numbers 1F103, 1F104, and 3F203; and 3) stability testing failures for [redacted] Amino Acid Cervical Cream finished products, lot numbers 1F103, 2F103, and 3F104.

4. Your release of drug product for distribution did not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release as required by 21 CFR 211.165(a). In addition, you failed to follow SOP #603-03, Evaluating and Investigation of Out of Specification Results. For example, [redacted] of finished drug product, Amino Acid Cervical Cream, NS #2219, were released based on passing retest results. The original tests of the [redacted] yielded OOS results for the active ingredient, Cysteine. The batches were released for distribution without an investigation being conducted.

5. Failure to perform stability testing to determine the appropriate expiration dating period as required by 21 CFR 211.166(b). For example, your firm does not have stability data to support the two-year expiration date used for Cypress Urea Chlorophyllin Debriding Ointment, NS #2315, or a three-year expiration date for the same product, batch # 1F103.

6. Failure to follow a written stability program designed to assess the stability characteristics of drug products to support a two-year expiration dating period as required by 21 CFR 211.166(a). In particular, your stability results failed to support the two-year expiration date as required by 211.137. For example, [redacted] of Amino Acid Cervical Cream, NS #2219, were placed on stability at [redacted] and [redacted] Failing results were reported for the active ingredient, Cysteine, and failing results were reported for various test intervals for inactive ingredients. Similarly, [redacted] of Cypress Papain Urea Chlorophyllin, NS #2315, were placed on stability at [redacted] and [redacted] Again, failing results were reported for the active ingredients, Urea, Papain, and Chlorophyllin Copper, and there were missing results at various test intervals. You also failed to perform stability testing at the recommended test intervals, [redacted] and [redacted] months for the Debriding Ointment and Cervical Cream.

7. Failure to establish the reliability of the suppliers' test results through full testing as required by 21 CFR 211.84(d)(2). For example, you did not perform full testing of all items listed on your suppliers' COA for Urea, Chlorophyllin Sodium Copper USP, Inositol, Cysteine, L-methionine, Oleoresin Capsicum, Lidocaine Hydrochloride, and Hydrocortisone Acetate.

8. Failure to evaluate, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures as required by 21 CFR 211.180(e).

Also, Amino Acid Cervical Cream and Papain-Urea-Chlorophyllin Ointment are drugs within the meaning of Section 201(g) of the Act, 21 U.S.C. § 321(g), because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. Further, they are "new drugs" within the meaning of Section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for their labeled uses. Under Sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced into or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for the drug. Your sale of Amino Acid Cervical Cream and Papain-Urea-Chlorophyllin Ointment without such approved applications violates these provisions of the Act.

Additionally, the above products are misbranded because, as prescription drugs, adequate directions cannot be written for them so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for use as required under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), and lacking required approved applications, they are not exempt from this requirement under 21 C.F.R. § 201.115.

The violations identified above are not intended to be an all-inclusive list of deficiencies at your facility. For additional information we refer you to the List of Observations contained in the Amended Form FDA-483, a copy of which was sent to you by letter dated October 26, 2005. It is your responsibility to ensure that all products manufactured by your firm are in compliance with the Act and with the GMP regulations. Federal Agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We acknowledge your written responses to the FDA-483 dated November 2, 2005, and January 6, 2006. In particular, you state that the firm has recalled all affected lots of Debriding Ointment and Amino Acid Cervical Cream, discontinued the current formulation of these products, quarantined existing inventory, and committed to initiate investigations where needed. However, you have not provided timetables for all of these corrective actions, and you have still failed to address many of the above-noted observations.

You should take prompt action to correct those deviations that remain and to provide documentation of corrections already taken, as requested above. Failure to promptly correct

these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct all the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action has not been completed, please provide a timetable within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, One Montvale Avenue, 4th floor, Stoneham, MA 02108, Attention Ann Simoneau, Compliance Officer.

Sincerely yours,

Gail T. Costello, District Director
New England District Office